

sAImone

Session Report

Conversation Export

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Role Medical Director

Organization AVTI

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Total Messages 15

Conversation History

Message 1: sAimone Response

Welcome, Nuno -- it's a pleasure to support you in your role as Medical Director at AVTI. I'll tailor responses to provide a balanced strategic and tactical perspective, with appropriate regional focus to support practical decision-making. Please share your current medical affairs challenge or question, and I'll help you work through it.

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Message 2: sAimone Response

Myasthenia Gravis Landscape Analysis

Scope assumption: Region was not specified in the prompt, so this single-pass landscape prioritizes **US, EU, UK, and Canada** for regulatory and access signals, and uses **global epidemiology/burden** where those data are more stable. **Verification date for time-sensitive items: March 18, 2026**

Executive Snapshot

- MG remains a **rare but increasingly recognized autoimmune neuromuscular disease**; the latest U.S. claims-based estimate reported **2021 prevalence 37.0 per 100,000** and **incidence 3.1 per 100,000**.
- Across global studies, MG epidemiology is heterogeneous, but the direction of travel is consistent: **higher measured prevalence over time**, likely driven by better diagnosis, aging populations, and improved survival.
- Clinical burden is substantial because weakness affects **ocular, bulbar, limb, and respiratory** muscle groups; acute exacerbations and crisis events are the main drivers of high-cost care.
- Humanistic burden is also high: in a multinational survey, employed patients reported **13.3% absenteeism, 26.7% presenteeism, 30.0% overall work impairment, and 39.2% non-work activity impairment**.
- Conventional management still centers on **pyridostigmine, corticosteroids, steroid-sparing immunosuppressants, thymectomy in selected patients, and IVIG/PLEX for rescue**.
- The treatment paradigm has materially shifted with targeted add-on biologics, especially **FcRn inhibitors and complement C5 inhibitors**.
- The market is now segmented less by “refractory MG” alone and more by **antibody status (AChR, MuSK), route/cadence preference, age band, and safety logistics**.
- As of March 18, 2026, the competitive set is broader in the **US** than it was in 2023, with **Imaavy** and **Uplizna** expanding the antibody-positive targeted landscape.
- **US regulatory access is ahead of HTA-backed access in Europe/UK**: NICE has not recommended efgartigimod for NHS use, ravulizumab's NICE appraisal was terminated, and CADTH has been materially more cost-sensitive than FDA/EMA.
- Economics remain a major gate: public list-price signals show annual treatment costs for targeted therapies commonly in the **high six-figure range**, and payers continue to focus on budget impact, sequencing, and comparator choice.
- Near-term competitive pressure will likely come from **label expansion, seronegative development, pediatric expansion, and immune-reset / cell-therapy programs** rather than from small changes within existing antibody-positive adult labels.
- The most important unresolved variable for launch or lifecycle planning is **country-by-country reimbursement reality**, not scientific plausibility alone.

1) Baseline & Impact

| Domain | Metric / finding | Value / effect | n / sample | Geography | Data cut-off / version | Status |
|-------------------|---|--|----------------------|---------------------------|---|---------------|
| Epidemiology | Mean global MG prevalence | 173.3 cases per million (95% CI 129.7-215.5) | 94 studies | Global | Literature through Feb 2024 | VERIFIED FACT |
| Epidemiology | Mean global MG incidence | 15.7 cases per million person-years (95% CI 11.5-19.9) | 94 studies | Global | Literature through Feb 2024 | VERIFIED FACT |
| Epidemiology | Diagnosed MG prevalence | 37.0 per 100,000 persons | Claims/EHR database | US | Calendar year 2021 | VERIFIED FACT |
| Epidemiology | Diagnosed MG incidence | 3.1 per 100,000 persons | Claims/EHR database | US | Calendar year 2021 | VERIFIED FACT |
| Clinical burden | Lifetime risk of myasthenic crisis | At least once in 15%-20% of patients | Literature synthesis | US-focused review context | Published 2022 | VERIFIED FACT |
| Humanistic burden | Work absenteeism | 13.3% | n=116 employed | Multinational | Survey fieldwork 2020; publication 2024 | VERIFIED FACT |
| Humanistic burden | Presenteeism | 26.7% | n=121 employed | Multinational | Survey fieldwork 2020; publication 2024 | VERIFIED FACT |
| Humanistic burden | Overall work impairment | 30.0% | n=110 employed | Multinational | Survey fieldwork 2020; publication 2024 | VERIFIED FACT |
| Humanistic burden | Non-work activity impairment | 39.2% | n=330 | Multinational | Survey fieldwork 2020; publication 2024 | VERIFIED FACT |
| Economic burden | All-cause healthcare cost | \$5,567 PMPM ; incremental +\$4,155 PMPM vs controls | Claims study | US | Publication 2024 | VERIFIED FACT |
| Economic burden | Acute event burden | \$17,330 PMPM in patients with MG exacerbation/crisis | Claims study | US | Publication 2024 | VERIFIED FACT |
| Economic burden | Annual all-cause cost in exacerbation cohort | \$43,734 | Retrospective study | US | Publication 2022 | VERIFIED FACT |
| Economic burden | Annual all-cause cost after crisis index date | \$173,956.99 | Retrospective study | US | Publication 2022 | VERIFIED FACT |

Abbreviations: CI = confidence interval; MG = myasthenia gravis; PMPM = per member per month; EHR = electronic health record.

Plain-text summary: MG remains numerically rare but operationally heavy. The disease burden is driven less by base prevalence alone than by the combination of chronic fluctuating disability, productivity loss, and acute

high-cost events. U.S. burden studies consistently show that inpatient care and crisis/exacerbation episodes are the major cost multipliers. For planning purposes, the key baseline reality is that MG behaves like a low-volume, high-complexity disease area rather than a simple rare-disease niche.

2) Paradigm / Workflow

| Step | Current practice / workflow | Key dependencies / standards | Biomarker / segment relevance | Data prov enance | Status |
|--------------------------------|---|---|---|--|---------------|
| Diagnosis | Confirm fatigable weakness; classify ocular vs generalized disease; assess severity and function | Specialist neuromuscular evaluation; standardized disease scales such as MG-ADL / QMG used in trials and practice | `AChR` and `MuSK` define key treatment-eligible subgroups; `LRP4` exists but remains less central to current labels | Consensus guidance + 2025 focused review | VERIFIED FACT |
| First-line symptomatic control | Pyridostigmine remains foundational symptomatic therapy | Symptom relief only; does not modify immune driver | Biomarker-agnostic | Consensus guidance / review | VERIFIED FACT |
| Disease modification | Corticosteroids plus steroid-sparing immunosuppressants remain conventional backbone | Time to effect may be months; steroid toxicity remains a major limitation | Biomarker-agnostic in routine use | Consensus guidance / review | VERIFIED FACT |
| Surgical pathway | Thymectomy remains relevant in selected patients | Best integrated within specialist pathway; timing and phenotype matter | Most relevant in selected `AChR`-positive generalized disease rather than all-comers | Consensus guidance / review | VERIFIED FACT |
| Rescue / acute care | IVIg or plasma exchange used for exacerbation or crisis | Hospital capability, timing, and respiratory monitoring are critical | Biomarker-agnostic rescue | Consensus guidance / review | VERIFIED FACT |
| Targeted add-on therapy | FcRn inhibitors and C5 inhibitors are now established targeted options | Often layered onto standard therapy rather than replacing it immediately | Current label access is strongest in antibody-positive gMG; `MuSK` access broader for some FcRn/B-cell approaches | 2025 review + regulator labels | VERIFIED FACT |
| FcRn pathway selection | Favored when IgG-lowering strategy is desired and route/cycle flexibility matters | IgG monitoring and infection vigilance matter in practice | Strongest current label support in `AChR`; some assets also include `MuSK` | 2025 review + FDA/EMA | VERIFIED FACT |
| Complement pathway selection | Favored in antibody-positive, complement-mediated disease biology and when fixed-interval dosing is preferred | Meningococcal vaccination / risk-mitigation is a practical prerequisite | Most directly aligned to `AChR`-positive disease | 2025 review + regulator labels | VERIFIED FACT |
| Practical sequencing | Route and cadence increasingly influence choice: IV q8w, IV q2w, SC weekly cycles, SC daily self-injection | Site-of-care economics and patient preference now matter more than before | Antibody subtype narrows feasible options first; convenience differentiates within class second | 2025 review + labels | INFERENCE |
| Off-label practice | Rituximab and other immunosuppressive strategies remain part of real-world care, especially in difficult-to-control disease | Jurisdiction and center practice vary materially | Particularly discussed in `MuSK`-positive disease, but usually not formally labeled | 2025 review | VERIFIED FACT |

Abbreviations: IVIG = intravenous immunoglobulin; QMG = Quantitative Myasthenia Gravis; MG-ADL = Myasthenia Gravis Activities of Daily Living; SC = subcutaneous; IV = intravenous.

Plain-text summary: The conventional MG workflow still starts with symptom control and broad immunosuppression, but the practical treatment algorithm has changed. Antibody status now functions as a real access gate, not just a diagnostic label. After biomarker gating, the next differentiators are safety logistics, route/cadence, and payer feasibility. The paradigm is therefore shifting from “late refractory rescue” toward “earlier targeted add-on selection in active antibody-positive disease.”

3) Competitive Set: On-Market vs Roadmap

| Asset / brand | MOA / modality | Current status (verified 2026-03-18) | Eligible population / label signal | Route / cadence | Key efficacy data* | Differentiators | Key risks / constraints | Confidence |
|---|-------------------------------------|--------------------------------------|---|---|--|--|--|------------|
| Soliris (eculizumab) | C5 complement inhibitor | US/EU on market | US: adult gMG; EU: refractory gMG with `AChR` antibody, including pediatric 6y+ | IV; maintenance every 2 weeks | Pivotal numeric effect not extracted in this pass; regulatory approval established | First complement-mover; deep clinical familiarity | Meningococcal risk-management; infusion burden; high cost | High |
| Ultomiris (ravulizumab) | Long-acting C5 complement inhibitor | US/EU on market | Adult `AChR`-positive gMG | IV; loading then q8 weeks maintenance | Week-26 MG-ADL change -3.1 vs -1.4 placebo ; treatment effect -1.6 (95% CI -2.6 to -0.7), p<0.001 ; sample size NR in retrieved source | Lowest administration frequency among marketed C5 inhibitors | Vaccination / meningococcal logistics; HTA headwinds | High |
| Vyvgart / Vyvgart Hytrulo (efgartigimod) | FcRn inhibitor | US/EU on market | Adult `AChR`-positive gMG | IV weekly x4 per cycle, or SC weekly x4 per cycle | ADAPT: MG-ADL responders in cycle 1 44/65 (68%) vs 19/64 (30%) ; OR 4.95 (95% CI 2.21-11.53), p<0.0001 | Strong foundational FcRn evidence; IV and SC optionality | Cyclic dosing can create re-treatment planning complexity; HTA cost-effectiveness pressure | High |
| Rystiggo (rozanolixizumab) | FcRn inhibitor | US/EU on market | Adult `AChR`-positive or `MuSK`-positive gMG | SC infusion once weekly for 6-week cycle | FDA pivotal dataset n=200 ; primary endpoint MG-ADL change at Day 43; exact delta NR in retrieved official source | One of the few approved options spanning both `AChR` and `MuSK` in adult gMG | Cycle-based treatment; headache/infusion logistics in practice | Moderate |
| Zilbrysq (zilucoplan) | Macrocyclic peptide C5 inhibitor | US/EU on market | Adult `AChR`-positive gMG | Daily SC self-injection | FDA pivotal dataset n=174 ; primary endpoint MG-ADL change at Week 12; exact delta NR in retrieved official source | Only marketed self-injected daily C5 option; no infusion center dependency | Daily adherence burden; complement safety logistics | High |

| Asset / brand | MOA / modality | Current status (verified 2026-03-18) | Eligible population / label signal | Route / cadence | Key efficacy data* | Differentiators | Key risks / constraints | Confidence |
|---|---------------------------------|--|---|-----------------------------------|---|---|--|------------|
| Imaavy (nipocalimab) | FcRn blocker | US on market; EU authorized | US: adult and pediatric 12y+ `AChR`/`MuSK` positive; EU: adult and adolescent 12y+ `AChR`/`MuSK` positive | IV; maintenance q2 weeks | FDA pivotal dataset n=196 adults ; 24-week randomized trial; exact treatment delta NR in retrieved official source | Broader age/antibody coverage than earlier FcRn entrants; sustained q2w regimen | Infusion model; market entry into a now crowded targeted class | High |
| Uplizna (inebilizumab) | Anti-CD19 B-cell depletion | US gMG on market; EU positive CHMP opinion, EC decision pending | US: adult `AChR` or `MuSK` positive gMG; EU: positive opinion for same | IV; low-frequency maintenance | Sponsor-reported Week-26 MG-ADL -4.2 vs -2.2 placebo, p<0.0001 ; sample size NR in retrieved source | Distinct B-cell depletion mechanism; long interval appeal | EU not yet fully converted to EC authorization for gMG as of verification date | Moderate |
| Telitacicept | BLyS/APRIL dual-target biologic | Roadmap | Phase 3 gMG study active | Trial-based | ClinicalTrials.gov Phase 3; efficacy readout not extracted here | Novel B-cell/plasma-cell axis beyond current FcRn/C5 classes | Development / regulatory risk | Moderate |
| Efgartigimod IV in seronegative gMG (ADAPTSERON) | FcRn inhibitor | Roadmap | Phase 3 active, not recruiting; seronegative gMG | Trial-based | ClinicalTrials.gov: primary completion actual 2025-06-30; study completion est. 2027-06 | Could expand FcRn market beyond current antibody-positive labels | Seronegative biology may dilute effect and payer enthusiasm | Moderate |
| KYV-101 / CABA-201 / MuSK-CAART | CAR-T / CAAR-T cell therapy | Roadmap | Early-to-mid stage development | One-time / cell therapy paradigms | Phase 2/3 or phase 1/2 studies active | Potential immune-reset positioning, not just chronic suppression | Manufacturing, safety, durability, and access uncertainty | Moderate |

\ If exact effect size / CI / p-value was not retrievable from the official source in this pass, it is marked NR.*

Abbreviations: CI = confidence interval; EC = European Commission; FcRn = neonatal Fc receptor; IV = intravenous; NR = not retrieved; SC = subcutaneous.

Plain-text summary: The marketed MG field is no longer a two-brand category. It is now a multi-class market defined by FcRn, complement, and emerging B-cell depletion. Competitive differentiation is increasingly practical rather than purely mechanistic: antibody coverage, dosing cadence, self-administration, infusion burden, and payer credibility now matter as much as topline efficacy. The next real market pivot is likely to come from broader-population expansion and immune-reset strategies, not from incremental within-class messaging alone.

4) Policy / Regulatory / Standards

| Topic | Current status | Recent change / timing | Practical constraint | Verified on | Confidence |
|-----------------------------------|--|--|---|-------------|---------------------------------------|
| FDA treatment landscape | US now includes multiple targeted approvals across FcRn, C5, and B-cell depletion approaches | Additions since 2023 include Imaavy (Apr 29, 2025) and Uplizna gMG label presence by late 2025/early 2026 evidence set | US access is label-permissive relative to HTA markets, but payer controls remain likely | 2026-03-18 | High for Imaavy; Moderate for Uplizna |
| EMA treatment landscape | EU authorized set includes Vyvgart, Rystiggo, Zilbrysq, Ultomiris, Soliris, Imaavy for defined gMG populations | Imaavy entered EU as a newer option; Uplizna has CHMP positive opinion for gMG but EC decision was still pending in retrieved source | EU label granularity remains important; some assets keep narrower refractory wording or adult-only scope | 2026-03-18 | High |
| Biomarker-linked regulation | Labeling remains tightly linked to antibody subgroups, especially `AChR` and `MuSK` | Broadest recent movement has been toward `MuSK` inclusion and adolescent expansion for selected assets | Any unqualified "all gMG" positioning is too broad in most jurisdictions | 2026-03-18 | High |
| NICE (England) - efgartigimod | Not recommended for NHS use within marketing authorization | Published June 4, 2025 | Main issue was cost-effectiveness and uncertainty in target population representation | 2026-03-18 | High |
| NICE - ravulizumab | Appraisal terminated ; no NICE recommendation | Published December 20, 2023 | Sponsor withdrew evidence submission; local commissioning logic may still be used case by case | 2026-03-18 | High |
| CADTH - efgartigimod | Recommend reimburse with conditions | 2024 recommendation set | Requires neurologist oversight and price reduction; not for concomitant use with rituximab or complement inhibitors | 2026-03-18 | High |
| CADTH - ravulizumab | Do not reimburse | 2023 recommendation | Clinical benefit acknowledged, but comparator and value concerns remained | 2026-03-18 | High |
| Safety / risk-management standard | Complement inhibitors require meningococcal risk management in practice and labeling context | Ongoing, class-defining | This is an operational barrier to rapid uptake and may influence site-of-care choice | 2026-03-18 | High |
| Evidence standard | Conventional guidance still anchors care to symptom control, immunotherapy, thymectomy where appropriate, and rescue therapy during crisis | No newer global consensus update retrieved in this pass beyond 2020 international guidance | Medical strategy should distinguish approved targeted use from off-label rituximab / immunosuppressant use | 2026-03-18 | High |

Abbreviations: CADTH = Canada's Drug Agency; CHMP = Committee for Medicinal Products for Human Use; EC = European Commission; HTA = health technology assessment; NHS = National Health Service.

Plain-text summary: The regulatory environment is moving faster than the reimbursement environment. FDA and EMA have clearly expanded the set of approved targeted options, but UK and Canadian HTA bodies remain cost-constrained and comparator-sensitive. In practice, this means regulatory approval is necessary but not sufficient for access. Any planning assumption that "approved = broadly reimbursed" would be too aggressive in MG.

5) Economics

| Economic dimension | Signal | Value / outcome | Unit / currency | Geography | Data cut-off / version | Status |
|--------------------------|---|---|-----------------|-----------|---|---------------|
| Disease cost burden | Incremental cost burden of gMG | +\$4,155 PMPM vs matched controls | USD | US | Published 2024 | VERIFIED FACT |
| Disease cost burden | Mean gMG spend | \$5,567 PMPM | USD | US | Published 2024 | VERIFIED FACT |
| Acute-event cost burden | Mean spend in patients with exacerbation/crisis | \$17,330 PMPM | USD | US | Published 2024 | VERIFIED FACT |
| Annual cost burden | Previously diagnosed gMG all-cause cost | \$24,941.47/year | USD | US | Published 2022 | VERIFIED FACT |
| Annual cost burden | Newly diagnosed gMG all-cause cost | \$26,419.20/year | USD | US | Published 2022 | VERIFIED FACT |
| Annual cost burden | Exacerbation cohort all-cause cost | \$43,734.15/year | USD | US | Published 2022 | VERIFIED FACT |
| Post-crisis burden | Post-crisis all-cause cost | \$173,956.99/year | USD | US | Published 2022 | VERIFIED FACT |
| Public list price signal | Vyvgart annual cost | 298,304-447,456/year | CAD list price | Canada | CADTH table current to review publication | VERIFIED FACT |
| Public list price signal | Ultomiris annual cost | 569,108 first year; 523,503 subsequent years | CAD list price | Canada | CADTH table current to review publication | VERIFIED FACT |
| Public list price signal | Soliris annual cost | 709,966 first year; 696,615 subsequent years | CAD list price | Canada | CADTH table current to review publication | VERIFIED FACT |
| Budget impact signal | Vyvgart projected public plan impact | ~379 million over 3 years | CAD | Canada | CADTH recommendation publication | VERIFIED FACT |
| HTA value signal | Efgartigimod in NHS England | Not cost-effective at submitted assumptions | Qualitative | UK | NICE 2025 | VERIFIED FACT |
| HTA value signal | Ravulizumab in Canada | Not recommended for reimbursement | Qualitative | Canada | CADTH 2023 | VERIFIED FACT |

Abbreviations: CAD = Canadian dollars; PMPM = per member per month; HTA = health technology assessment.

Plain-text summary: The economic story in MG is dominated by two facts: acute events are extremely expensive, and new targeted therapies are also extremely expensive. That creates a classic access tension in which payers may recognize unmet need and clinical value but still resist broad reimbursement at list price. The

result is likely continued focus on line-of-therapy control, value-based sequencing narratives, and strong pressure for price concessions or restricted use criteria.

VERIFIED FACTS vs INFERENCES

VERIFIED FACTS

- **[High]** MG prevalence and incidence are rising in measured datasets, including the latest U.S. 2021 claims-based estimate.
- **[High]** Clinical and economic burden is substantial, with crisis/exacerbation driving disproportionate cost.
- **[High]** Current standard care still includes symptomatic therapy, immunosuppression, thymectomy in selected patients, and IVIG/PLEX for rescue.
- **[High]** The current approved targeted class mix includes FcRn and complement inhibition, with B-cell depletion now entering the US competitive set.
- **[High]** NICE and CADTH remain more restrictive than FDA/EMA on MG biologic access.
- **[Moderate]** Uplizna has entered the US gMG market and has EU positive opinion but not yet EC authorization in the retrieved EU source set.

INFERENCES

- **[Moderate]** The market is transitioning from a “refractory rescue” paradigm to a **segmented chronic targeted-care market**.
- **[Moderate]** Convenience factors such as self-administration, infusion frequency, and site-of-care will increasingly shape competitive share within clinically credible classes.
- **[Moderate]** EU commercial uptake is likely to remain slower than US uptake because reimbursement friction is now a more important barrier than pure regulatory availability.
- **[Needs verification]** Real-world payer policy in individual countries and accounts will likely prohibit or strongly discourage concurrent use of multiple targeted MG biologics, but this should be checked locally by plan and market.

Open Unknowns / Requires Verification

- Country-by-country reimbursement and formulary reality outside UK/Canada.
- Net price / confidential discount structures by market.
- Exact pivotal numerical endpoint deltas for some assets were not retrievable from the official sources in this pass and are marked **NR** where applicable.
- Relative uptake trends by line of therapy and switch behavior in 2025-2026.
- Any local procurement, tender, or hospital pathway rules for infusion-center vs self-administered products.

Notes

- This output distinguishes **approved** from **investigational** uses where relevant, but conventional MG care still includes substantial **off-label** practice in many regions.
- Because the prompt did not specify geography, policy and economics are most robust for **US / EU / UK / Canada**; extrapolation beyond these markets should be treated cautiously.
- For a next-pass deep dive, the highest-value extensions would be: **country-level access matrix**, **KOL / center-of-excellence map**, or **asset-by-asset evidence and differentiation deck**.

References (accessed March 18, 2026)

Primary / authoritative external sources

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- architecture_map_specification.json routing and evidence-validation logic.
- landscape_analysis_v3.json scope and evidence-gating schema.

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Message 3: User

Dianthus is initiating a Phase 3 gMG trial in mid-2026, with top-line results expected in 2H 2028, we are researching and planning for a disease awareness campaign for their asset(s), consider this from a franchise perspective please. give me a phase 1

Message 4: sAimone Response

Phase 1 -- User Intent & Therapy Context Enrichment

Project context: Dianthus is preparing a **pre-Phase 3 / peri-Phase 3 disease awareness strategy** in **generalized myasthenia gravis (`gMG`)**, with **claseprubart (`DNTH103`)** / **claseprubart franchise** as the relevant investigational asset context. **Verified time-sensitive date: March 18, 2026**

1) Parsed Intent & Context

| Field | Phase 1 interpretation |
|------------------------|--|
| Decision problem | Define the external environment for a compliant disease awareness campaign in `gMG` before Dianthus begins Phase 3 in mid-2026 |
| Asset context | Claseprubart (`DNTH103`) , an investigational active `C1s` inhibitor ; company now refers to the asset as claseprubart |
| Franchise lens | Not just one `gMG` asset: position the opportunity as part of a broader neuromuscular / classical pathway franchise spanning `gMG`, `CIDP`, and `MMN` |
| Lifecycle stage | Phase 2 data available; Phase 3 start planned mid-2026; topline expected 2H 2028 |
| Planning goal | Build disease-state legitimacy, sharpen unmet-need territory, identify stakeholder priorities, and define what awareness space is credibly "ownable" without becoming pre-promotional |
| Geographic assumption | Global framing with US / EU / UK / Canada emphasis because current regulatory, HTA, and advocacy signals are strongest there |
| Output scope | Phase 1 only: situational analysis, landscape, competitive context, regulatory environment, SWOT, TOWS, stakeholder map |
| Evidence gates applied | Regulatory claims anchored to regulators where possible; pipeline claims anchored to company + ClinicalTrials.gov; disease burden triangulated with peer-reviewed literature and public bodies; awareness compliance anchored to FDA / ABPI / EFPIA plus internal MAPS rare disease guidance |

2) Executive Summary

- `gMG` remains a **high-burden rare autoimmune disease** with meaningful diagnostic delay, fluctuating disability, acute deterioration risk, and high emotional / operational burden.
- The **awareness problem is still real**, even in a more crowded treatment market: diagnosis delay, misdiagnosis, under-recognition of fluctuating symptoms, and fragmented care pathways remain visible.
- Dianthus is entering a market that has shifted from “few options” to **multi-class competition**, with approved **FcRn, C5 complement**, and now **B-cell depletion** options in the US.
- That means a future Dianthus disease awareness effort cannot rely on “there are no treatments” or a thinly veiled branded narrative; it must focus on **disease education, patient journey, diagnosis, burden, and treatment decision complexity**.
- The most attractive unbranded space for Dianthus is not generic “MG awareness,” but **targeted awareness around antibody-positive generalized disease, diagnostic burden, symptom fluctuation, crisis prevention, and the need for sustained control with practical treatment fit**.
- From a franchise perspective, the strongest long-term narrative platform is likely **classical pathway-driven autoimmune neuromuscular disease**, not a single-asset story.
- Company-reported Phase 2 data for claseprubart are encouraging, but they remain **investigational, sponsor-reported, and not yet sufficient for promotional-style clinical value narratives**.
- A disease awareness campaign in this window should therefore be judged less by product pull-through and more by whether it improves **stakeholder understanding, earlier recognition, quality of insight capture, and franchise credibility**.
- The external environment is favorable for awareness because patient advocacy is organized, awareness-month infrastructure already exists, and rare-disease communities value authentic education.
- The external environment is challenging because HCP attention is fragmented, patient groups are sensitive to authenticity, and regulators / self-regulatory bodies will scrutinize any campaign that implicitly points to an investigational product.
- Phase 1 therefore supports a strategy centered on **credible, community-relevant disease-state leadership** rather than overt mechanism-led pre-positioning.
- The key Phase 2 handoff question will be: **which awareness territory best advances the franchise while staying clearly non-promotional?**

3) Landscape Analysis

3.1 Disease / Burden / White-Space Landscape

| Theme | Verified fact | Strategic implication for disease awareness | Confidence |
|--------------|--|--|------------|
| Epidemiology | Global systematic review confirms MG is rare but heterogeneous, with increasing measured prevalence across studies | Awareness can still credibly focus on under-recognition rather than rarity alone | High |

| Theme | Verified fact | Strategic implication for disease awareness | Confidence |
|--------------------|---|--|------------|
| US burden | Recent US claims-based work supports a meaningful diagnosed population and substantial economic burden | The condition is rare enough to need awareness, but common enough for a scaled national campaign to matter | High |
| Diagnostic delay | European `gMG` patients with diagnosis delay over 1 year had worse burden, more initial misdiagnoses, more fatigue/anxiety/depression, and worse MG-QoL-15r | Diagnosis delay is one of the strongest compliant awareness territories | High |
| Symptom complexity | MG symptoms fluctuate and can involve ocular, bulbar, limb, and respiratory muscles | Awareness must teach pattern recognition and referral triggers, not just “muscle weakness” | High |
| Acute burden | Exacerbations and crisis remain major clinical and economic stressors | Messaging can legitimately focus on consequences of delayed recognition and poor control | High |
| Patient journey | Rare-disease MAPS guidance emphasizes gaps in natural history, diagnosis, and patient journey as core pre-launch priorities | Disease awareness should be tightly linked to patient-journey mapping and insight generation | High |
| Advocacy ecosystem | MGFA remains a large, organized advocacy presence; MG Awareness Month infrastructure is active and visible | There is existing community energy to partner with, but authenticity and role clarity matter | High |
| Care fragmentation | `gMG` crosses neurology, neuro-ophthalmology, emergency medicine, primary care, respiratory care, and infusion / specialty pharmacy workflows | Franchise awareness must span more than the treating neurologist audience | Moderate |

Phase 1 readout: the core unmet need is not simply “more awareness of MG exists.” It is **better-quality awareness:** earlier suspicion, faster referral, better antibody / subtype understanding, clearer recognition of generalized disease burden, and better appreciation of fluctuating symptoms and deterioration risk.

3.2 Current Dianthus / Franchise Context

| Item | Current status | Evidence detail | Confidence |
|--------------------------|--|---|------------|
| Lead `gMG` asset | Claseprubart (`DNTH103`) in `gMG` | Dianthus pipeline page states Phase 3 start expected mid-2026 , topline 2H 2028 | High |
| Mechanism | Investigational active `C1s` inhibitor with SC administration intent | Company describes selective inhibition of active `C1s`, with self-administered SC positioning | Moderate |
| Phase 2 program | MaGic Phase 2 completed in `AChR`-positive adult `gMG` | ClinicalTrials.gov: randomized, blinded, placebo-controlled study; last update posted Oct 7, 2025 | High |
| Phase 2 sample | n=65 enrolled | Company enrollment release exceeded original target of 60 | High |
| Phase 2 topline efficacy | Company reported placebo-adjusted MG-ADL improvement 1.8 points at Week 13 for 300 mg Q2W; p=0.0113 | Sponsor-reported; not yet validated in full peer-reviewed paper retrieved in this pass | Moderate |
| Franchise narrative | Dianthus explicitly frames claseprubart as the foundation of a neuromuscular franchise (`gMG`, `CIDP`, `MMN`) | Company investor / SEC materials support this framing | High |

Interpretation: disease awareness should be designed so that it helps **gMG now**, but also builds a reusable franchise platform for **complement-driven autoimmune neuromuscular disease** more broadly.

4) Competitive Intelligence Analysis

4.1 Current `gMG` Competitive Set

| Segment | Current market reality | Implication for Dianthus awareness strategy | Confidence |
|-----------------------------|---|---|------------------|
| FcRn inhibitors | `Vyvgart / Hytrulo`, `Rystiggo`, and `Imaavy` have expanded targeted competition | Awareness cannot assume physicians view MG as untreated or under-innovated; narrative must move up to disease complexity and treatment fit | High |
| C5 inhibitors | `Soliris`, `Ultomiris`, and `Zilbrysq` establish complement inhibition as a validated treatment class | Dianthus benefits from class legitimacy, but cannot present "complement is new" as a unique awareness idea | High |
| B-cell depletion | `Uplizna` adds another mechanism and broadens competitive framing | The market is increasingly about which patients need which biology / regimen , not whether biologics matter at all | Moderate to High |
| Administrati on convenience | Competitors now span IV, SC cycle-based, daily SC, and less frequent maintenance regimens | Treatment convenience has become a meaningful decision axis; disease awareness can legitimately highlight treatment-burden complexity without naming products | High |

| Segment | Current market reality | Implication for Dianthus awareness strategy | Confidence |
|-----------------------|--|---|------------|
| Line-of-therapy drift | The field is moving toward broader biologic use, not only late refractory rescue | Awareness should address modern treatment pathways and decision bottlenecks, not outdated “last resort” framing | Moderate |

4.2 Dianthus Positioning vs Market Direction

| Dimension | Dianthus / claseprubart context | Competitive relevance | Phase 1 implication |
|---------------------|---|--|---|
| Biology | Upstream classical pathway logic in `AChR`-positive disease is biologically credible | Offers a differentiated complement story if later confirmed clinically | Use this as internal framing, not external disease-awareness shorthand |
| Population | Current `gMG` development is centered on `AChR`-positive disease | This is the largest biologically relevant complement subgroup | Awareness can responsibly support antibody-positive disease understanding |
| Dosing ambition | Company signals Q2W / Q4W SC aspiration for Phase 3 | Convenience would matter if later validated | Too early for outward value narrative; retain as internal opportunity only |
| Safety aspiration | Company highlights no boxed-warning / REMS aspiration in its own materials | Could matter vs incumbent complement agents | Not appropriate as disease-awareness lead because unapproved and unverified by regulators |
| Franchise extension | Same molecule / pathway is being developed in other neuromuscular autoantibody diseases | Helps justify franchise-led awareness architecture | Makes a “classical pathway neuromuscular disease” platform more durable |

4.3 Competitive Threat Matrix

| Threat | Why it matters | Threat level | Franchise implication |
|------------------------------|---|----------------|--|
| Class crowding | Multiple approved targeted therapies already shape neurologist expectations | High | Harder to “own” generic innovation narrative |
| Awareness crowding | Advocacy groups and incumbents already run community education | High | Dianthus must be additive, not duplicative |
| Thinly veiled promotion risk | Investigational asset plus disease awareness can be perceived as pre-branding | High | Governance must be stringent from the start |
| Evidence gap vs incumbents | Competitors have labels, pivotal publications, and real-world experience | High | Awareness must lead with disease need, not comparative insinuation |
| Franchise halo upside | Success in `gMG` could elevate trust across `CIDP` / `MMN` | Medium to High | High payoff if awareness platform is built at franchise level |

CI conclusion: Dianthus is not entering an empty awareness space. It is entering a space where **the disease is still under-recognized, but the treatment market is no longer underdeveloped**. That makes **diagnosis, patient journey, and care-pathway education** more defensible than any campaign territory that implies an

unapproved product solution.

5) Regulatory / Policy / Standards Overview

5.1 Disease-State Campaign Guardrails

| Jurisdiction / standard | Verified rule | Campaign meaning |
|----------------------------|---|--|
| FDA / OPDP | FDA states that lawful help-seeking ads describe a disease or condition but do not recommend or suggest a specific drug | US disease awareness can be compliant if it remains genuinely unbranded and non-linking |
| FDA / OPDP | FDA also warns that disease-awareness content can create misleading product impressions if conflated with drug promotion | Visual identity, URLs, call-to-action pathways, retargeting, and adjacency to corporate / branded content all matter |
| ABPI Code | UK code permits disease-awareness / public-health campaigns if they encourage the public to seek treatment or health checks and do not promote a specific prescription medicine | UK campaigns are feasible, but must stay clearly disease-led |
| EFPIA Code | EFPIA requires compliant interactions and transparency across stakeholder engagement, with national code overlay | EU deployment needs country-by-country adaptation, especially around public-facing materials and patient-group support |
| Rare-disease MAPS guidance | Start early with disease awareness, diagnosis initiatives, and broad stakeholder engagement in rare disease | Disease awareness is strategically appropriate at this stage if separated from product claims |

5.2 Product / Market Regulatory Context

| Topic | Current state | Relevance |
|-----------------------|---|--|
| Dianthus asset status | Claseprubart is investigational in `gMG`; no approval identified in retrieved FDA / EMA sources | No product efficacy / safety value claims should appear in public disease awareness |
| Market maturity | FDA and EMA have multiple targeted `gMG` approvals in FcRn and complement classes; US has recently added `Imaavy` and `Uplizna` | Disease-state education must acknowledge a modern therapeutic landscape |
| HTA environment | NICE and CADTH remain cost-sensitive in `gMG`, even where clinical innovation is recognized | Payer-oriented disease awareness should not presume easy access or simple value narratives |

Regulatory Phase 1 conclusion: A Dianthus disease awareness effort is **strategically legitimate** but **compliance-sensitive**. The safest framing is **help-seeking, diagnosis, burden, and care navigation**, with strong firewalls from any investigational product narrative.

6) SWOT -- Franchise Disease Awareness in `gMG`

| Strengths | Weaknesses |
|---|--|
| Dianthus is early enough to shape the disease narrative before Phase 3 and well before launch | Asset remains investigational; evidence package is not yet pivotal-grade |
| `AChR`-positive disease has strong biological rationale for classical pathway relevance | Market is already crowded with approved targeted agents |
| Rare-disease MAPS guidance strongly supports early awareness, patient engagement, and diagnosis initiatives | Awareness can easily be perceived as surrogate pre-branding |
| Franchise logic across `gMG`, `CIDP`, and `MMN` allows a broader neuromuscular platform | Dianthus lacks the installed-field and advocacy footprint of larger incumbents |
| Company-reported Phase 2 signal is directionally supportive | No retrieved full peer-reviewed pivotal-style publication for claseprubart in `gMG` yet |
| Opportunities | Threats |
| Own the conversation on diagnosis delay, fluctuating symptoms, and pathway fragmentation | Incumbents can outspend or out-scale on education and advocacy support |
| Build credibility with patient organizations and COEs before Phase 3 recruitment / readout | Community skepticism if campaign feels asset-adjacent |
| Frame franchise around classical pathway autoimmune neuromuscular disease | Regulatory / self-regulatory scrutiny if creative or media routing implies product linkage |
| Use insights to improve Phase 3 readiness, evidence generation, and future launch positioning | Rapid competitor label evolution could narrow future differentiation space |
| Support better understanding of antibody-positive disease and care escalation triggers | HCP attention is fragmented; "another MG awareness campaign" may struggle to break through |

7) TOWS Matrix

| TOWS quadrant | Strategic implication |
|---------------|--|
| S-O | Use early-stage agility plus biologic rationale to build a high-trust, disease-first neuromuscular awareness platform that can later support the franchise |
| S-T | Use the scientific legitimacy of complement biology to inform internal narrative design, but keep outward awareness anchored in diagnosis and burden to avoid promotion risk |
| W-O | Offset limited late-stage product evidence by leaning into stakeholder insight generation, patient-journey work, and education on diagnostic bottlenecks |
| W-T | Avoid any campaign architecture that looks like mechanism-seeding for an investigational asset; crowding plus regulation makes that the highest-risk failure mode |

8) Stakeholder Mapping, Identification & Tiering

8.1 Priority Stakeholder Map

| Tier | Stakeholder group | Why they matter now | Franchise value |
|--------|--|--|---|
| Tier 1 | Neuromuscular specialists / MG treaters / COEs | Diagnose, subtype, treat, recruit to trials, shape scientific narrative | Highest direct impact on both disease awareness credibility and future franchise adoption |
| Tier 1 | Patients, caregivers, patient advocacy organizations | Define real burden, diagnostic odyssey, educational need, and trust threshold | Essential for authentic disease awareness in rare disease |
| Tier 1 | External experts / key MG investigators | Influence congress narrative, referral patterns, and evidence interpretation | High leverage for both `gMG` and broader neuromuscular franchise |
| Tier 2 | Community neurologists, neuro-ophthalmologists, emergency / acute care clinicians | Often see early or decompensating patients before referral | Critical for awareness around delayed diagnosis and deterioration |
| Tier 2 | Medical and scientific societies | Provide educational legitimacy and dissemination routes | Important for scale and credibility |
| Tier 2 | Internal medical, field medical, patient advocacy, evidence, and market-access teams | Must keep disease-awareness boundaries and insight loops aligned | Core to franchise consistency |
| Tier 3 | Payers / HTA / policy stakeholders | Less central for public awareness, but relevant for burden framing and eventual access narrative | More important as program nears readout / launch |
| Tier 3 | Digital patient communities / online support ecosystems | Early source of real-world concerns and language | Useful for insight capture and message testing, with governance |

8.2 MAPS-Aligned Pillars, Tactics, Metrics for This Context

| Type | Highest-relevance items for Phase 1 |
|-------------------|--|
| Strategic pillars | `patient_advocacy`, `hcp_education`, `scientific_exchange`, `field_medical`, `digital_omnichannel`, `insight_management`, `medical_information`, `evidence_generation` |
| Tactics | `patient_advocacy_engagement`, `hcp_education_program`, `msl_field_engagement`, `omnichannel_campaign`, `insight_capture_synthesis`, `medical_information_response`, `peer_reviewed_publication`, `rwe_registry` |
| Metrics | `stakeholder_reach_percentage`, `digital_content_engagement_rate`, `medical_education_impact_score`, `msl_engagement_rate`, `insight_quality_score`, `insight_to_action_conversion_rate`, `patient_reported_outcome_integration`, `guideline_inclusion_tracking` |

8.3 Stakeholder-Specific Observations

| Stakeholder | Current need signal | Awareness relevance | Confidence |
|-------------------------|--|----------------------------|------------|
| Patients / carers | Diagnosis delay, symptom dismissal, fatigue / QoL burden, crisis anxiety | Very high | High |
| COEs / experts | Evolving treatment landscape, biology segmentation, complex sequencing | Very high | High |
| Community neurologists | Earlier recognition and referral triggers | High | High |
| Non-neurology referrers | Bulbar / ocular / respiratory symptom recognition | Moderate to high | Moderate |
| Advocacy organizations | Practical education, support navigation, trust, transparency | Very high | High |
| Payers / HTA | Burden and value evidence, not public disease awareness per se | Moderate now, rising later | High |

9) Phase 1 Synthesis

Facts

- Dianthus expects to start a **Phase 3 `gMG` trial in mid-2026** with topline in **2H 2028**.
- Claseprubart is **investigational**, with company-reported Phase 2 data in `AChR`-positive `gMG`.
- The `gMG` market already contains multiple targeted approved therapies across FcRn, complement, and B-cell depletion.
- Diagnostic delay and patient burden remain material and well-supported awareness territories.
- Rare-disease MAPS guidance strongly supports early disease awareness, patient engagement, and stakeholder insight capture.

Rules Applied

- Disease-awareness framing must remain **non-promotional** and **non-product-suggestive**.
- Pre-approval public communications cannot imply that an investigational product is the implied solution.
- Rare-disease planning should give disproportionate weight to patients / caregivers / advocacy groups and COEs.
- Franchise framing is allowed internally, but outward communications should be disease-first.

Inferences

- Dianthus's most defensible awareness territory is **diagnosis + burden + pathway complexity**, not mechanism-forward pre-positioning.
- A franchise-level platform is more durable if it is built around **classical pathway autoimmune neuromuscular disease** internally, while staying disease-specific externally.
- If Phase 3 begins mid-2026, the 2026-2028 window should be used to build **credibility, insight quality, and stakeholder trust**, not just reach.

Open Unknowns

- Country-specific public-communications restrictions beyond US/UK/EU high-level codes.
- Which exact stakeholder segment offers the biggest untreated awareness gap: community neurology, ophthalmology, emergency care, or patient/family channel.
- How much room exists for a new MG disease awareness entrant without community fatigue.
- Whether Dianthus intends a single global platform or regionally distinct awareness architectures.

Recommended Next Checks

- 1 Validate which **diagnostic bottleneck** is most actionable: symptom recognition, antibody testing, referral, or crisis escalation.
- 2 Map the **existing MG awareness footprint** by advocacy groups and incumbents to avoid duplication.
- 3 Define a **franchise-safe message architecture** separating disease burden, biology education, and investigational asset content.
- 4 Build a **country governance grid** for US, UK, EU priority markets before creative development.
- 5 Pressure-test the narrative with **patients / advocacy groups / COEs** before any outward activation.

Further Refining Query Options

- Build the **Phase 2 strategic foundation** for the campaign
- Define the **best disease-awareness territory** Dianthus can own without pre-promotional risk
- Create a **stakeholder-specific message house** for patients, carers, COEs, and community neurology
- Build a **country-by-country compliance matrix** for US / UK / EU disease-awareness activity
- Develop a **competitive white-space map** versus argenx, Alexion/AstraZeneca, UCB, J&J, Amgen
- Create a **KOL / COE prioritization framework** for `gMG`
- Build a **franchise narrative architecture** across `gMG`, `CIDP`, and `MMN`
- Define **Phase 1 success metrics** and insight capture schema
- Map **patient advocacy partners** and event / congress opportunities through 2026-2027
- Assess **risk scenarios** if Phase 3 timelines or competitor labels shift

Type `proceed` to continue to Phase 2, or specify any area you would like expanded.

Notes

- This Phase 1 output is intentionally **landscape-first** and avoids detailed tactical execution.
- Sponsor-reported claseprubart efficacy / safety observations are treated as **investigational and not yet regulator-validated**.
- “Franchise perspective” here refers primarily to **claseprubart across neuromuscular autoimmune indications**, with `DNTH212` only peripheral at this stage.

References (accessed March 18, 2026)

Internal framework / planning sources

- architecture_map_specification.json -- routing, constraint flow, query logic
- data_sources.json -- evidence hierarchy and source-validation rules
- data_presentation.json -- study / metric presentation structure
- landscape_analysis_v3.json -- allowed scope and evidence gates
- pillars_v2.json -- relevant pillars including HCP education, field medical, digital omnichannel, patient advocacy, medical information
- tactics_taxonomy_v2.json -- relevant tactics including MSL field engagement, HCP education program, omnichannel campaign
- metrics_v2.json -- relevant metrics including stakeholder reach, digital engagement, insight quality, insight-to-action conversion
- MAPS Strategic Planning Roadmap (2019)
- MAPS Rare Diseases White Paper
- MAPS Launch Excellence guidance
- MAPS External Scientific Engagement guidance
- MAPS Measuring Value and Impact guidance
- MAPS Strategic Integrated Evidence guidance

Primary / authoritative external sources

- Dianthus Therapeutics. Approach and Pipeline. <https://dianthustx.com/approach-and-pipeline/>
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- ClinicalTrials.gov. NCT06282159, MaGic Phase 2 study of DNTH103 / claseprubart in adults with generalized myasthenia gravis. <https://clinicaltrials.gov/study/NCT06282159>

Disease / burden / patient journey

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Biology / mechanism context

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- Frontiers in Immunology. Targeting autoimmune mechanisms by precision medicine in Myasthenia Gravis. <https://www.frontiersin.org/journals/immunology/articles/10.3389/fimmu.2024.1404191/full>

Current market / regulatory context

- FDA. Drug Trials Snapshot: IMAAVY. <https://www.fda.gov/drugs/drug-approvals-and-databases/drug-trials-snapshot-imaavy>

- FDA. FDA Approves New Treatment for Myasthenia Gravis (Vyvgart).
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- FDA. Novel Drug Approvals for 2025.
<https://www.fda.gov/drugs/novel-drug-approvals-fda/novel-drug-approvals-2025>
- EMA EPAR pages for Vyvgart, Ultomiris, Soliris, Zilbrysq, Rystiggo, Imaavy
- NICE. Efgartigimod for treating antibody-positive generalised myasthenia gravis.
<https://www.nice.org.uk/guidance/ta1069/>
- NICE. Ravulizumab for treating generalised myasthenia gravis (terminated appraisal).
<https://www.nice.org.uk/guidance/ta940/>
- CADTH / Canada's Drug Agency materials on efgartigimod and ravulizumab in gMG

Disease-awareness compliance / public communications

- FDA. Correct Help-Seeking Ad.
<https://www.fda.gov/drugs/prescription-drug-advertising/correct-help-seeking-ad>
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- EFPIA Code. <https://www.efpia.eu/relationships-code/the-efpia-code/>

Advocacy / community ecosystem

- Myasthenia Gravis Foundation of America. <https://myasthenia.org/>
- MGFA Awareness Month resources. <https://myasthenia.org/mg-awareness-month-resources/>
- MGFA 2025 toolkit.
<https://myasthenia.org/wp-content/uploads/2025/04/MG-Awareness-Month-Toolkit-2025.pdf>
- MG Alliance. <https://themgalliance.org/>
- Myasthenia Gravis Association. <https://mgassociation.org/>

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Message 5: User

draft a franchise narrative architecture across gMG, CIDP, and MMN and conduct another web pass for anything that might change this plan materially, also consider EU5 please

Message 6: sAimone Response

Franchise Narrative Architecture -- `gMG`, `CIDP`, `MMN`

Context: Dianthus / claseprubart franchise planning **Geographic lens:** EU5 + US context check, with live web re-validation for anything that could materially alter the architecture **Verification date:** March 18, 2026

Executive Summary

- The franchise should **not** use a single undifferentiated “complement story” across `gMG`, `CIDP`, and `MMN`. It needs **one umbrella thesis** and **three disease-specific branches**.
- The strongest umbrella is **autoimmune neuromuscular disease marked by delayed diagnosis, fluctuating or progressive disability, treatment burden, and need for more durable, practical disease control**.
- The biology can unify the franchise internally, but externally the safer architecture is **patient journey + burden + treatment-friction + unmet need**, not mechanism-first messaging.
- `gMG` is now a **crowded biologic market**, so the franchise story in `gMG` cannot be “innovation is arriving”; it must be “important unmet need persists despite more options.”
- `CIDP` changed materially for Europe in 2025 because **Vyvgart now has an EMA-approved CIDP indication**. Any franchise narrative that treats CIDP as an IVIG-only category is now outdated.
- `MMN` remains the cleanest white-space indication from a narrative standpoint because **dependence on immunoglobulin remains high** and alternative approved options remain limited.
- One material EU-wide change is the **ongoing human normal immunoglobulin shortage expected through June 2026**. This materially strengthens any franchise theme around treatment dependency, access fragility, and care disruption in `CIDP` / `MMN`.
- In EU5, access signals are **heterogeneous**. France, Germany, Italy, Spain, and the UK are not telling one simple story; the narrative architecture must be **modular by country**.
- Germany has a **nipocalimab AMNOG process underway in `gMG`** with publication starting April 1, 2026 and decision expected mid-June 2026, which could quickly shift the German `gMG` access conversation.
- The UK remains relatively restrictive in `gMG`: **efgartigimod is not routinely available on the NHS, while CIDP appraisal work for efgartigimod is in progress**.
- Therefore the most defensible franchise platform is: **“Across autoimmune neuromuscular disease, patients still face delayed recognition, disabling symptoms, and burdensome treatment pathways; future progress must improve both disease control and treatment fit.”**
- The biggest risk to the plan is overreaching on a single biology-led narrative where evidence maturity differs across the three diseases.

1) Another Web Pass -- What Could Materially Change the Plan

| Item | Why it matters | Materiality to architecture | Confidence |
|---|---|---|------------------|
| EMA approval expansion for Vyvgart in `CIDP` | `CIDP` in Europe is no longer just an immunoglobulin / steroid / plasma-exchange story | High -- requires `CIDP` narrative to acknowledge biologic innovation already exists | High |
| EU immunoglobulin shortage ongoing, expected through June 2026 | `CIDP` and `MMN` patients remain dependent on immunoglobulin access and supply continuity | High -- strengthens a franchise theme around treatment-pathway fragility and burden | High |
| Germany AMNOG process started for nipocalimab in `gMG` | A near-term German access decision could shift `gMG` reference framing in EU5 | High for Germany; medium for broader EU5 | High |
| France HAS positions Rystiggo as important but minor added value and recommends expert-network validation | Confirms specialist-gated, value-sensitive access behavior in `gMG` | Medium to high -- supports country-modular EU5 messaging | High |
| Italy reimbursement activity in `gMG` including Rystiggo reimbursement and Vyvgart registry modifications | Shows practical access is shaped by registry design, not EMA label alone | Medium | High |
| Spain has already surfaced Imaavy indication and CIDP Vyvgart appraisal work in national processes | Confirms Spanish access pathway is moving and should be tracked separately | Medium | Moderate to High |
| UK NICE: efgartigimod not routinely available for `gMG`; CIDP appraisal in development for July 2026; nipocalimab appraisal in development | UK narrative must stay highly access-aware and not assume rapid franchise uptake | High for UK | High |
| EMA concept paper on clinical investigation of medicines for myasthenia gravis opened in 2026 | Signals evolving trial / evidence expectations in `gMG` | Medium -- more relevant to evidence strategy than public narrative, but still important | Moderate |
| MMN competition is still limited, but argenx / empasiprubart has EU orphan designation and an MMN clinical program | `MMN` is attractive white space, but not empty | Medium | Moderate |
| No regulator-hosted approval found for claseprubart in any of the three indications | Dianthus remains fully investigational across the franchise | Very high -- all outward framing must remain disease-state and non-promotional | High |

Bottom line from the second pass

The plan **does not need a full rewrite**, but it **does need tightening** in three places:

- 1 **`CIDP` must be updated** to reflect existing FcRn competition in Europe.
- 2 **`MMN` should be elevated** as the clearest treatment-burden / immunoglobulin-dependence narrative space.

- 3 **EU5 cannot be treated as one market;** country modules are required.

2) Draft Franchise Narrative Architecture

A. Architecture Design Principle

Build the franchise as a **3-layer narrative system**:

- 1 **Franchise thesis**
- 2 **Disease-family narrative**
- 3 **Disease-specific modules** for `gMG`, `CIDP`, and `MMN`

This avoids the main failure mode: forcing one biological claim across diseases with different evidence maturity and competitive realities.

B. Level 1 -- Franchise Thesis

| Component | Draft |
|------------------------------------|---|
| Franchise thesis (internal) | Autoimmune neuromuscular diseases remain defined by delayed recognition, disabling weakness, treatment burden, and inconsistent long-term control; the next era should improve both disease control and treatment practicality across biologically relevant subgroups. |
| Strategic role | Creates a reusable platform across `gMG`, `CIDP`, and `MMN` without overclaiming that the same biology is equally validated in all three |
| What it does well | Connects diagnosis, burden, treatment friction, and innovation need |
| What it must avoid | "All three are the same disease family with one proven mechanism." That would overstate current evidence |

Recommended internal summary statement

Dianthus is building a neuromuscular autoimmune franchise around diseases where patients still face meaningful unmet need despite existing treatment options, especially when care is delayed, burdensome, or dependent on fragile treatment pathways.

C. Level 2 -- Disease-Family Narrative

| Component | Draft language | Use case |
|--------------------------------------|--|---|
| Core disease-family statement | Across autoimmune neuromuscular disorders, patients often live with weakness that disrupts function, independence, and quality of life, while clinicians navigate diagnostic uncertainty, disease heterogeneity, and burdensome treatment pathways. | Franchise umbrella |
| Burden pillar | Function loss is experienced differently across diseases, but in all three the impact on daily living is outsized relative to prevalence | Patient / advocacy / HCP |
| Pathway pillar | Earlier recognition, more precise classification, and more practical long-term management remain important gaps | HCP / systems / policy |
| Treatment pillar | Existing therapies have advanced care, but access, administration burden, supply dependence, and durability remain important challenges | HCP / payer / policy |
| Future-facing pillar | The next wave of progress should improve not only response, but also predictability, convenience, and continuity of care | Internal / expert / investor-facing medical framing |

Plain-language external version

These are rare disorders, but the burden is not rare for the people living with them. Earlier recognition, better disease understanding, and more practical care pathways still matter.

D. Level 3 -- Disease-Specific Narrative Modules

1) `gMG` module

| Element | Draft |
|------------------------------------|---|
| Disease truth | `gMG` is a fluctuating, potentially severe neuromuscular disease in which symptom variability, delayed diagnosis, and treatment complexity still create real unmet need |
| What has changed | `gMG` is now a biologically active market with FcRn, complement, and B-cell options in some regions |
| What still matters | Even with more options, patients may still face delayed recognition, symptom volatility, crisis risk, and complex treatment sequencing |
| Narrative role in franchise | `gMG` is the most advanced and visible proof-of-concept market , but not the cleanest white-space awareness space |
| Best narrative territory | Persistent unmet need despite progress |
| Avoid | “`gMG` is still untreated / under-innovated” or any near-product mechanism-seeding |

2) `CIDP` module

| Element | Draft |
|------------------------------------|--|
| Disease truth | `CIDP` is a disabling immune-mediated neuropathy where relapse or progression, functional decline, and long-term treatment dependence remain central issues |
| What has changed materially | The EMA-approved `CIDP` indication for Vyvgart means Europe now recognizes a non-immunoglobulin biologic pathway in `CIDP` |
| What still matters | Many patients still cycle through or remain dependent on corticosteroids and immunoglobulins; relapse prevention, practical maintenance, and functional preservation remain high-value needs |
| Narrative role in franchise | `CIDP` is the bridge disease : less crowded than `gMG`, but no longer a pre-biologic category |
| Best narrative territory | Relapse / progression control with lower treatment friction |
| Avoid | Framing `CIDP` as a static IVIG-only landscape |

3) `MMN` module

| Element | Draft |
|-------------------------------------|---|
| Disease truth | `MMN` is a rare, frequently under-recognized motor neuropathy with substantial functional impact, especially in hand and arm function |
| Current treatment reality | Immunoglobulin remains the dominant therapeutic backbone; alternatives remain limited |
| What has become more salient | EU immunoglobulin shortages make dependency on IVIG even more operationally important |
| Narrative role in franchise | `MMN` is the highest-unmet-need / cleanest franchise white space |
| Best narrative territory | Functional impact + dependence on chronic immunoglobulin + need for more sustainable options |
| Avoid | Overstating late-stage competitive emptiness; emerging pipeline exists |

3) Recommended Narrative Hierarchy

| Level | Narrative statement | Audience fit |
|---------------------------------|--|---|
| Master franchise headline | Autoimmune neuromuscular diseases still carry a disproportionate burden because diagnosis, treatment burden, and long-term disease control remain difficult. | Enterprise / corporate / medical strategy |
| Clinical franchise sub-headline | Progress now depends on improving both biological control and treatment practicality across distinct but related diseases. | Internal / expert / publication planning |
| `gMG` branch | In `gMG`, more options have improved care, but important unmet need persists in recognition, symptom control, and treatment fit. | HCP / advocacy / policy |
| `CIDP` branch | In `CIDP`, biologic innovation has begun, yet relapse, progression, and maintenance burden remain unresolved for many patients. | HCP / expert / EU5 access |
| `MMN` branch | In `MMN`, dependence on immunoglobulin and limited alternatives keep functional preservation and treatment continuity at the center of care. | HCP / advocacy / policy |

4) Audience-Specific Franchise Adaptation

| Audience | What to emphasize | What to de-emphasize |
|------------------------------------|--|---------------------------------------|
| Neuromuscular experts / COEs | Disease heterogeneity, subgrouping, treatment burden, evolving evidence, care pathway gaps | Broad public-style awareness language |
| Community neurologists / referrers | Recognition, referral triggers, practical disease differentiation, impact of delay | Complex mechanism-first content |
| Patient organizations / caregivers | Function, fatigue, unpredictability, daily burden, treatment logistics, continuity of care | Competitive class detail |
| Payers / policy / HTA | Burden, treatment dependency, access fragility, real-world function, continuity of care | Promotional clinical enthusiasm |
| EU5 affiliates | Country-specific access maturity and specialist gating | Single pan-EU narrative |
| Internal franchise team | Shared architecture, lexicon, evidence ladder, message governance | Disease silos |

5) EU5 Country Adaptation Layer

| Market | What the narrative must reflect | Planning implication |
|----------------|--|--|
| Germany | Fast-moving benefit assessment environment; nipocalimab `gMG` procedure active with near-term milestones | Keep German `gMG` narrative highly current and HTA-aware |
| France | Specialist-network validation culture and modest incremental-value framing for some `gMG` entrants | Use stronger expert-center and pathway language, not broad mass-access assumptions |
| Italy | Registry and reimbursement mechanics can materially affect use conditions | Include operational-access language in narrative support materials |
| Spain | IPT / REvalMed positioning is important for practical access interpretation | Build Spain-specific evidence framing modules |
| UK | NICE remains selective in `gMG`; CIDP appraisal work continues | Keep UK narrative conservative on access and value assumptions |

EU5 architecture rule

Use **one franchise backbone** but **five market-specific overlays**. Do **not** deploy one “EU narrative deck” without country edits.

6) Lexicon Recommendations

| Use | Preferred language | Avoid |
|-----------|---|---|
| Franchise | autoimmune neuromuscular disease, care pathway burden, treatment dependency, functional impact, continuity of care | platform-in-a-product, best-in-class, franchise winner in external medical materials |
| `gMG` | persistent unmet need despite therapeutic progress | few options, untreated market |
| `CIDP` | relapsing or progressive active disease, maintenance burden, functional preservation | IVIG-only disease |
| `MMN` | limited alternatives, functional dependence, ongoing immunoglobulin reliance | no competition, empty market |
| Mechanism | investigational classical pathway approach (internal) | External disease-state language that implies claseprubart is the solution |

7) Strategic Risks to the Narrative Architecture

| Risk | Why it matters | Mitigation implication |
|---|--|--|
| Over-unifying biology across all 3 diseases | Evidence maturity is strongest in `gMG`, less settled across the franchise | Keep biology strongest in internal strategy, lighter in external disease narrative |
| Underestimating `CIDP` competition | EMA-approved Vyvgart changes the category | Update all `CIDP` materials to post-2025 reality |
| Missing IVIG shortage implications | This affects `CIDP` and `MMN` care reality in Europe | Integrate treatment continuity / supply fragility into burden framing |
| Treating EU5 as one market | HTA / reimbursement signals differ materially | Build country modules |
| Drifting into pre-promotional framing | Claseprubart remains investigational in all 3 indications | Maintain disease-state / unmet-need separation and governance |

8) Recommended Final Draft Narrative Architecture

Franchise narrative

Across autoimmune neuromuscular diseases, patients still face delayed recognition, disabling weakness, burdensome treatment pathways, and uneven long-term control. The next era of care must improve not only disease control, but also treatment practicality, continuity, and fit for patients' real lives.

`gMG` narrative

In generalized myasthenia gravis, therapeutic progress has expanded options, but patients and clinicians still face symptom volatility, diagnostic delay, crisis risk, and complex treatment decisions.

`CIDP` narrative

In CIDP, biologic innovation has entered the treatment landscape, yet many patients still live with relapse risk, progression, and the burden of chronic maintenance therapy.

`MMN` narrative

In MMN, functional impairment and long-term dependence on immunoglobulin remain central challenges, reinforcing the need for more durable and practical treatment pathways.

Unifying franchise close

Different diseases. Shared patient burden. Shared need for better long-term disease control and treatment fit.

9) Facts / Rules Applied / Inferences / Open Unknowns

Facts

- Claseprubart remains investigational across `gMG`, `CIDP`, and `MMN`.
- EMA now lists Vyvgart for both `gMG` and `CIDP`.
- EMA reports an ongoing EU shortage of human normal immunoglobulins, expected through June 2026.
- Germany has started the `gMG` benefit assessment process for nipocalimab.
- France, Italy, Spain, and the UK show materially different access / appraisal signals in `gMG`.

Rules Applied

- No claim of approval or superiority was made for claseprubart.
- Country-level access statements were kept specific where official sources were available.
- Franchise narrative was separated from disease-specific evidence maturity.
- Narrative architecture was kept disease-state first and non-promotional.

Inferences

- `MMN` is likely the strongest franchise white space from a narrative perspective.
- `CIDP` is now strategically more contested in Europe than a pre-2025 plan would assume.
- The IVIG shortage increases the relevance of “care continuity” and “treatment dependence” across `CIDP` / `MMN`.

Open Unknowns

- Final German and UK decisions for upcoming `gMG` / `CIDP` appraisals.
- Country-specific reimbursement depth beyond the public documents retrieved here.
- Whether Dianthus intends one global franchise lexicon or a separate EU5 lexicon.

Next Checks

- 1 Build a **country-specific EU5 narrative overlay** with do / do-not language.
- 2 Convert this architecture into a **scientific communications platform**: objectives, lexicon, statements, and proof points.
- 3 Pressure-test the franchise wording with **EU5 affiliate medical leads**.
- 4 Build a **competitor narrative heatmap** across `gMG`, `CIDP`, and `MMN`.
- 5 Create a **compliance-separated external vs internal message matrix**.

Notes

- This is a **franchise narrative architecture**, not a promotional claims document.
- Biology should be used as a **supporting internal logic**, not as the sole external unifying frame.
- EU5 treatment and access dynamics are moving quickly enough that a **quarterly refresh cadence** is advisable.

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Message 7: sAimone Response

Real-Time Competitive Intelligence Report

Project context inferred: Dianthus / clareprubart franchise planning across `gMG`, `CIDP`, and `MMN`, viewed through an **awareness campaign + franchise narrative** lens **Primary geographies emphasized: EU5 + US**, with global signals included when they materially affect competitive posture **Verification date for time-sensitive items: March 18, 2026**

Executive Summary

- The franchise battlefield is **not one market**; it is **three linked but structurally different markets**: crowded biologic competition in `gMG`, newly contested biologic expansion in `CIDP`, and still-limited-option dependency in `MMN`.
- **argenx** is the current **franchise leader** across the combined space. It is the commercial leader in `gMG`, the first targeted mover in `CIDP`, and the most advanced challenger in `MMN`.
- **Dianthus** remains the only company in this set with a deliberately aligned `**gMG**` + `**CIDP**` + `**MMN**` **neuromuscular franchise story** built around one investigational asset, **claseprubart**, but it is still fully investigational.
- In `gMG`, the market has broadened materially: FcRn, complement, and B-cell depletion players now all have approved positions in at least one major market.
- Recent `gMG` changes that matter most: **UPLIZNA FDA approval in December 2025 and EC approval in February 2026**, plus continuing **Imaavy** expansion and **VYVGART seronegative gMG PDUFA on May 10, 2026**.
- In `CIDP`, the most important change is that **Vyvgart is now EMA-approved**. That makes any “CIDP is still an IVIG-only category” narrative obsolete.
- In `MMN`, **IVIG remains the practical market leader / standard of care**, but **empasiprubart** is now the most advanced late-stage competitive threat, with **Phase 3 primary completion estimated September 2026**.
- The **EU immunoglobulin shortage** is a major environmental amplifier for `CIDP` / `MMN` narratives focused on treatment dependence, supply fragility, and continuity of care.
- From an awareness-campaign perspective, **argenx and J&J are the most active evidence-and-narrative competitors**, not just product competitors. Both are investing in comparative framing, real-world evidence, and congress visibility.
- **UCB** is narrower than argenx but still important because it owns two distinct `gMG` mechanisms and sustains a visible neuromuscular presence through AANEM / MGFA scientific channels.
- **AstraZeneca / Alexion** remains the legacy complement incumbent in `gMG`, but its growth threat is lower than FcRn and B-cell entrants because the market is shifting toward broader-label, convenience-sensitive competitors.
- **Sanofi** is the most important pure-`CIDP` pipeline threat outside argenx and J&J; its **riliprubart** Phase 3 program is a meaningful 2026 watch item.
- There is still **no completed head-to-head pivotal readout** that fully resolves class leadership in `gMG`; however, **J&J has initiated a comparative nipocalimab vs efgartigimod study**, and comparative evidence wars are accelerating.
- For Dianthus, the biggest external risks are **franchise crowding in `gMG`**, **accelerating biologic normalization in `CIDP`**, and **argenx’s cross-indication scale**.
- The biggest opportunity remains **franchise coherence**: no other visible competitor currently matches Dianthus’s single-asset neuromuscular storyline across all three diseases in quite the same way.

Competitive Landscape Table

| Company | Product / asset | Indication(s) in current project scope | MOA / platform | Current status (as of 2026-03-18) | Market position | Key differentiation | Key vulnerabilities | Confidence |
|-----------------|---|--|------------------------|---|--|---|--|------------|
| argenx | `Vyvgart / Hytrulo` (`efgartigi mod`) | `gMG`, `CIDP` | FcRn blocker | Approved in `gMG` across major markets; approved in `CIDP` in US / Japan / China and EMA-authorized in Europe | Current franchise leader | First-mover FcRn scale, broad evidence engine, large patient base, strong medical affairs footprint | Increasing class competition; transition-risk narratives in `CIDP`; premium-access scrutiny | High |
| argenx | `empasirubarb` (`ARGX-117`) | `MMN`, `CIDP` | C2 inhibitor | Phase 3 MMN; Phase 3 CIDP | Most advanced direct franchise pipeline threat to Dianthus | Cross-indication complement expansion, early MMN lead, strong neuromuscular congress presence | Still unapproved; late-stage execution risk in two neuropathy indications | High |
| Dianthus | `claseprubart` | `gMG`, `CIDP`, `MMN` | Active `C1s` inhibitor | `gMG` Phase 3 planned mid-2026; `CIDP` Phase 3 ongoing; `MMN` Phase 2 ongoing | Emerging franchise challenger | One-asset franchise coherence, SC ambition, complement-pathway differentiation | No approvals; thinner publication base; lower commercial / congress scale than argenx or J&J | High |
| UCB | `Rystiggo` (`rozanolixizumab`) | `gMG` | FcRn blocker | Approved in US / EU / Japan | Established `gMG` specialist player | Covers `AChR` and `MuSK`; strong patient-centric positioning | Narrower franchise breadth; no visible late-stage `CIDP` / `MMN` asset in retrieved set | High |
| UCB | `Zilbrysq` (`zilucoplan`) | `gMG` | C5 inhibitor peptide | Approved in US / EU / Japan | Dual-mechanism `gMG` competitor | Daily SC self-administration option; complement choice within one company | Daily injection burden; limited franchise extension visible here | High |

| Company | Product / asset | Indication(s) in current project scope | MOA / platform | Current status (as of 2026-03-18) | Market position | Key differentiation | Key vulnerabilities | Confidence |
|---------------------------------------|-------------------------------|--|---------------------------------|---|--|--|--|------------|
| AstraZeneca / Alexion | `Ultomiris` / `Soliris` | `gMG` | C5 inhibitors | Approved in `gMG` | Legacy complement incumbents | Strong complement heritage; established expert familiarity | Narrower labels vs newer entrants; infusion / vaccination burden; payer pressure | High |
| Johnson & Johnson | `Imaavy` (nipo-calimab) | `gMG`, `CIDP` pipeline | FcRn blocker | FDA-approved in `gMG`; EU pathway advanced / approved in Europe; `CIDP` Phase 2/3 ongoing | Fast-rising broad-label challenger | Broad antibody-positive population, adolescent inclusion, sustained-control narrative, aggressive comparative strategy | IV regimen; still earlier than argenx in `CIDP`; comparative claims rely partly on indirect evidence | High |
| Amgen | `Uplizna` (inebilizumab) | `gMG` | Anti-CD19 B-cell depletion | FDA approved Dec 2025; EC approved Feb 2026 | New B-cell entrant in `gMG` | Twice-yearly maintenance after loading; distinct mechanism | No `CIDP` / `MMN` footprint here; newer launch with limited neuromuscular franchise breadth | High |
| Sanofi | `riliprubart` | `CIDP` | C1s inhibitor | Phase 3 ongoing; H2 2026 readout guidance | High-priority `CIDP` pipeline threat | Same pathway family as Dianthus; large-company execution capacity | No current approval; commercial / narrative proof in neuromuscular disease still pending | High |
| Standard of care / non-branded | IVIG / SCIG / steroids / PLEX | `CIDP`, `MMN`, `gMG` background | Broad immunomodulation / rescue | Established | Still defines baseline in neuropathy indications | Familiarity, installed use, reimbursement pathways | Supply shortage, chronic burden, variability, limited precision | High |

Clinical Trial Tracking and Catalyst Calendar (12-24 Months)

| Timing | Company / asset | Indication | Trial / NCT | Phase | Key endpoint(s) / design | Enrollment / status | Expected catalyst | Impact |
|---|--|-------------------------|-----------------------------------|-------------------|--|------------------------------------|---|-----------|
| Apr 18-22, 2026 | argenx / `Vyvgart`, `empasiprubart`, `adimanebart` | `gMG`, `CIDP`, pipeline | AAN 2026 | N/A | New MG / CIDP data, biomarker and RWE analyses | Confirmed congress plan | New data may reinforce market leadership and broaden label narrative | High |
| May 10, 2026 | argenx / `Vyvgart` | seronegative `gMG` | FDA review | Regulatory | Label expansion decision | Priority review timeline disclosed | Could materially broaden leader position in `gMG` | Very high |
| Mid-2026 | Dianthus / `claseprubarit` | `gMG` | registrational Phase 3 initiation | Phase 3 | Pivotal design start | Company-guided | Franchise inflection point; shifts Dianthus from Phase 2 story to registrational competitor | Very high |
| 2H 2026 | Dianthus / `claseprubarit` | `CIDP` | CAPTIVATE | Phase 3 | Interim responder analysis | Ongoing | Earliest cross-franchise proof beyond `gMG` | Very high |
| 2H 2026 | Dianthus / `claseprubarit` | `MMN` | MoMeNtum | Phase 2 | Topline data | Ongoing | Critical for `MMN` franchise credibility | Very high |
| 2H 2026 | Sanofi / `riliprubart` | `CIDP` | Phase 3 program | Phase 3 | Pivotal readout guidance | Ongoing | Could validate a rival `C1s` story before Dianthus matures | Very high |
| Jun 2026 (expected) | J&J / `nipocalimab` | `gMG` Germany access | G-BA process | HTA | Benefit assessment decision | Process active | Could shift EU5 `gMG` access narrative | High |
| Jul 29, 2026 (scheduled topic milestone) | argenx / `Vyvgart` | `CIDP` UK | NICE topic | HTA | Appraisal milestone | In development | Important UK access signal for franchise messaging | High |
| Sep 2026 (estimated primary completion) | argenx / `empasiprubart` | `MMN` | NCT06742190 | Phase 3 | Compare empasiprubart vs IVIG | Estimated n=115; active | Most important late-stage `MMN` competitor catalyst | Very high |
| 2026 onward | J&J / `nipocalimab` vs `efgartigimod` | `gMG` | NCT07217587 | Comparative study | FcRn comparison / switch study | Newly initiated | Could shape comparative class perception even before definitive commercial settling | High |

| Timing | Company / asset | Indication | Trial / NCT | Phase | Key end point(s) / design | Enrollment / status | Expected catalyst | Impact |
|--------------------------------------|----------------------------|------------|-------------------------|-----------|-----------------------------------|---------------------|---|--------------------|
| 2027-05-14 primary completion est. | J&J / `nipocalimab` | `CIDP` | NCT05327114 | Phase 2/3 | Withdrawal design / relapse delay | Estimated n=201 | Major `CIDP` class-expansion threat | Very high |
| 2028 2H | Dianthus / `claseprubart` | `gMG` | planned Phase 3 topline | Phase 3 | Pivotal efficacy / safety | Future | Long-range defining event for franchise valuation | Very high |
| Patent expiries in next 12-24 months | ND in retrieved source set | N/A | N/A | N/A | N/A | ND | Should be added in next pass from Orange Book / SPC / investor legal review | Needs verification |

Abbreviations: ND = not determined in this pass; PLEX = plasma exchange.

Recent Readouts and Publication Monitoring

| Asset | Recent evidence signal | Source type | Key finding | Confidence |
|--------------------------------|--|--|---|------------|
| `efgartigimod` in `CIDP` | ADHERE publication | Peer-reviewed / PubMed | Reduced relapse risk versus placebo in CIDP responders; anchors `CIDP` biologic legitimacy | High |
| `nipocalimab` in `gMG` | Vivacity-MG3 publication / press | Peer-reviewed + company | Phase 3 positive in broad antibody-positive population; J&J pushing sustained-control differentiation | High |
| `inebilizumab` in `gMG` | MINT publication | Peer-reviewed / NEJM + company | Functional improvement in `AChR` + / `MuSK` + `gMG`; twice-yearly dosing is a major practical claim | High |
| `claseprubart` in `gMG` | AANEM 2025 oral presentation plan; sponsor topline release | Company + congress | Encouraging Phase 2 signal, but no full peer-reviewed pivotal-style paper retrieved in this pass | Moderate |
| `efgartigimod` in `gMG` | ADAPT SERON / OCULUS / Jr visibility at AAN 2026 | Company | Leader expanding into broader MG subtypes and earlier-stage populations | High |
| `gMG` comparative evidence war | ITCs / NMAs from argenx and J&J | Congress / company-sponsored analytics | Competitive debate is moving beyond label text to comparative effectiveness framing | Moderate |

Publication / authorship implication

The **publication leadership advantage currently sits with argenx, J&J, and Amgen**. Dianthus remains visible in congress-style disclosure but **not yet publication-dominant**.

Conference Presence and Scientific Visibility

| Company | Major neuromuscular visibility pattern | Interpretation |
|-----------------|--|---|
| argenx | Strong AAN 2026 presence; 40+ abstracts across MG / CIDP / MMN / IIM at AANEM 2025; aggressive real-world and biomarker layering | Clear share-of-voice leader |
| J&J | Multiple AAN 2025 abstracts; AANEM 2025 announcement of first FcRn-vs-FcRn comparative study | Most aggressive narrative challenger to argenx in `gMG` |
| UCB | AANEM 2025 + MGFA Scientific Session focus on Rystiggo / Zilbrysq outcomes | Sustained specialist visibility in `gMG`, narrower franchise width |
| Amgen | Late-breaking AAN 2025 MINT oral | New entrant building credibility quickly through marquee readout venues |
| Dianthus | AANEM 2025 oral for MaGic | High-quality but selective visibility; expert-led, not yet scale-led |
| Sanofi | CIDP-focused program visibility via pipeline / investor materials | Important `CIDP` threat, but lower neuromuscular congress presence retrieved in this pass |

Digital Engagement and Thought-Leader Patterns

| Company | HCP / patient support infrastructure observed | Competitive implication |
|-----------------|--|---|
| argenx | Dedicated Medical Affairs portal; My VYVGART Path access program; explicit use of digital + traditional media in annual report | Most mature omnichannel support ecosystem in franchise |
| UCB | ONWARD patient support for Rystiggo / Zilbrysq; disease-specific web assets | Strong patient-support and treatment-onboarding positioning |
| J&J | JNJ Medical Connect, congress poster libraries, comparative evidence amplification | Strong expert-facing digital medical ecosystem |
| Amgen | Amgen By Your Side for Uplizna | Fast-building launch support but narrower neuromuscular digital footprint than argenx/J&J |
| Dianthus | IR / congress-led visibility, not broad commercial-scale HCP digital presence | Appropriate for current stage, but lower digital share of voice |
| Alexion | Established label / safety infrastructure; less visible retrieved digital expansion signal in this pass | Legacy presence rather than fast-moving engagement |

Digital / KOL inference

- **argenx and J&J appear most aggressive in narrative shaping**, not just product communication.
- **Dianthus currently competes through scientific selectivity**, not scaled omnichannel reach.

Pricing / Access Snapshot

| Asset / company | Public pricing / access signal retrieved | Strategic read-through | Confidence |
|-------------------|--|---|------------|
| `Vyvgart` | CADTH public annual cost estimate approximately CAD 298k-447k depending on weight / use assumptions | High-cost biologic benchmark; price pressure remains real | High |
| `Ultomiris` | CADTH public annual cost estimate approximately CAD 569k first year / 523k subsequent | Reinforces premium rare-neuro threshold and payer sensitivity | High |
| `Soliris` | CADTH public annual cost estimate approximately CAD 710k first year / 697k subsequent | Legacy complement remains premium-priced and access-sensitive | High |
| `Vyvgart Hytrulo` | Company stated U.S. pricing parity to Vyvgart on a net annual revenue basis | Convenience innovation without overt price reset | Moderate |
| `gMG` UK access | NICE did not recommend efgartigimod for antibody-positive `gMG`; ravulizumab appraisal terminated | UK remains restrictive and evidence/value sensitive | High |
| EU5 access | France / Germany / Italy / Spain show heterogeneous access evolution for `gMG` entrants | EU5 messaging must be country-specific | High |
| Patient support | argenx, UCB, and Amgen all visibly operate access / support hubs | Patient-support infrastructure is now table stakes in rare-neuro launch execution | High |

Strategic Movements

| Company | Strategic movement | Why it matters |
|---|---|---|
| argenx | 2026 strategic priorities emphasize MG label expansion, CIDP growth, and pipeline depth including empasiprubart | Confirms broad franchise ambition, not a single-brand strategy |
| J&J | Launched comparative head-to-head study in `gMG` and continues cross-autoantibody expansion of `Imaavy` | Signals willingness to compete on comparative evidence, not just label breadth |
| Amgen | Rapidly expanded `Uplizna` from NMOSD / IgG4-RD into `gMG`; EC approval now secured | Brings large-company commercial scale to B-cell depletion in MG |
| Sanofi | Keeps riliprubart prominently in `CIDP` pipeline with H2 2026 readout focus | Serious `CIDP` pathway competitor, especially relevant to Dianthus because both are `C1s` stories |
| Dianthus | Continues to frame claseprubart as a neuromuscular franchise with three 2026 catalysts | Unique internal coherence, but still a pre-approval story |
| No material M&A / licensing event in retrieved set | None identified in this pass for this exact neuromuscular subset | Monitor, but not a current differentiator |

Strategic SWOT by Major Competitor

1) argenx

| Strengths | Weaknesses | Opportunities | Threats |
|--|--|--|--|
| Scale, first-mover advantage, cross-indication evidence engine, strong congress presence | Premium-access pressure; growing class competition | Seronegative `gMG`, ocular / pediatric expansion, `MMN` and `CIDP` complement pipeline | Class commoditization and comparative-evidence attacks |

2) Johnson & Johnson

| Strengths | Weaknesses | Opportunities | Threats |
|--|--|---|---|
| Broad antibody-positive `gMG` framing, large-company reach, comparative ambition | Later commercial entry than argenx; still building neuromuscular franchise depth | `CIDP` expansion, FcRn-class leadership challenge | If comparative study fails to differentiate meaningfully, premium narrative weakens |

3) UCB

| Strengths | Weaknesses | Opportunities | Threats |
|--|---|---|--|
| Dual-mechanism `gMG` portfolio, specialist credibility, patient-support infrastructure | Narrow franchise scope vs argenx / Dianthus | Deeper `gMG` subpopulation ownership, route-of-administration positioning | Being crowded out by broader-label or stronger-scale players |

4) Amgen

| Strengths | Weaknesses | Opportunities | Threats |
|---|--|---|---|
| Distinct B-cell mechanism, twice-yearly dosing story, large-company execution | No visible `CIDP` / `MMN` franchise adjacency here | Rapid `gMG` share capture via convenience + differentiation | Competes in a dense `gMG` field without broader neuromuscular franchise narrative |

5) Sanofi

| Strengths | Weaknesses | Opportunities | Threats |
|--|---|---|---|
| Large-scale development capability, late-stage `CIDP` asset, pathway relevance | No approved neuromuscular anchor in scope yet | If `CIDP` readout is positive, could become major neuropathy competitor | Pathway overlap may split investor / expert attention with Dianthus |

6) AstraZeneca / Alexion

| Strengths | Weaknesses | Opportunities | Threats |
|--|--|---|---|
| Long complement heritage, expert familiarity, installed base | Older infusion paradigm, narrower labels, less franchise expansion retrieved | Defend complement credibility with long-term experience | Newer agents erode differentiation on convenience and breadth |

Priority Watch List

| Asset / company | Why watch closely | Monitoring priority |
|---|--|---------------------|
| `Vyvgart` seronegative `gMG` / argenx | May broaden argenx's `gMG` lead materially | Critical |
| `empasiprubart` / argenx in `MMN` | Most advanced direct threat in `MMN` | Critical |
| `riliprubart` / Sanofi in `CIDP` | Same pathway family as Dianthus; H2 2026 readout | Critical |
| `nipocalimab` / J&J in `CIDP` | Could create a second strong FcRn pole in `CIDP` | High |
| `Uplizna` / Amgen in `gMG` | New mechanism and EU approval may accelerate market fragmentation | High |
| `Imaavy` / J&J head-to-head study | Comparative FcRn framing could reshape `gMG` class hierarchy | High |
| EU immunoglobulin shortage | Directly affects `CIDP` / `MMN` treatment continuity and narrative environment | High |
| Dianthus `CIDP` interim + `MMN` topline | Internal franchise-defining catalysts | Critical |

Weekly Alert Triggers

Regulatory

- FDA / EMA / CHMP / EC decisions for:
- `Vyvgart` seronegative `gMG`
- `nipocalimab` `gMG` EU / major HTA movement
- `Uplizna` country-level EU5 reimbursement progression
- `CIDP` filings / appraisals for `efgartigimod`, `nipocalimab`, `riliprubart`, `empasiprubart`

Clinical

- Any update to:
- `NCT06742190` `MMN` empasiprubart
- `NCT07091630` `CIDP` empasiprubart
- `NCT05327114` `CIDP` nipocalimab
- `NCT06290128` `CIDP` riliprubart
- Dianthus CAPTIVATE / MoMeNtum / `gMG` registrational start

Congress / publication

- AAN, AANEM, EAN, PNS, MGFA Scientific Session:
- oral vs poster upgrades
- new subgroup / long-term / RWE / biomarker data
- new indirect comparisons or class-comparison posters

Access / commercial

- NICE, G-BA, HAS, AIFA, AEMPS / REvalMed changes
- public payer / registry criteria changes
- IVIG shortage extension or resolution
- launch-support or patient-program expansion

Strategic / corporate

- new licensing, manufacturing, or sales-force signals
- leadership changes in rare disease / neurology
- financing events that extend or constrain Dianthus runway

VERIFIED FACTS vs INFERENCES

VERIFIED FACTS

- `Vyvgart` is the dominant cross-`gMG` / `CIDP` competitive anchor in the current landscape.
- `Imaavy` and `Uplizna` are now approved in `gMG` in the US, with Europe materially advancing / completed for those assets.
- `empasiprubart` is in Phase 3 for `MMN` and `CIDP`.
- `riliprubart` is in Phase 3 for `CIDP`, with H2 2026 readout guidance in company materials.
- `claseprubart` has active / planned programs in `gMG`, `CIDP`, and `MMN`.
- The EU human normal immunoglobulin shortage is an active macro factor.

INFERENCES

- argenx is likely the **market leader / standard setter** for the combined franchise space.
- J&J is the strongest current **narrative challenger** in `gMG`.
- `MMN` remains the cleanest whitespace for franchise differentiation, but argenx is the late-stage competitive leader there.
- Dianthus's strongest structural advantage is **franchise coherence**, not scale.

NEEDS VERIFICATION / FOLLOW-UP

- Exact net pricing and confidential contracting across EU5 and the US.
- Patent-expiry windows relevant to the next 12-24 months.
- Social-media reach metrics by competitor brand / medical affairs organization.
- Country-by-country reimbursement depth for newly approved `gMG` entrants.

Notes

- Investigational agents discussed here are **not approved** unless explicitly stated otherwise.
- Off-label use patterns exist in these diseases but were not the focus of this report.
- For awareness-campaign planning, the most important CI signal is **who is shaping the disease conversation**, not only who has label presence.

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Internal framework / guidance

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- 2025-maps-medical-strategy-f.pdf / strategic_medical_planning.pdf -- competitor analysis standards
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Message 8: User

give me a narrative extended analysis anchored to quantitative data on the session and plan so far.

Message 9: sAImone Response

Extended Narrative Analysis

Integrated synthesis of the session so far: disease landscape, Phase 1 framing, franchise narrative architecture, competitive intelligence, and EU5 implications **Verification date for time-sensitive items: March 18, 2026**

Executive Readout

The quantitative picture from the session points to one clear conclusion: **Dianthus should think and act like a franchise builder, but communicate like a disease-state leader.** The numbers show real unmet need across `gMG`, `CIDP`, and `MMN`, but they also show that the three indications are at very different competitive and access stages. That means the strategy should be **franchise-integrated at the platform level and indication-specific at the narrative and market-execution level.**

1) Quantitative Anchors From the Session

| Domain | Quantitative anchor | What it means strategically |
|--------------------------------------|---|---|
| Global MG prevalence | 173.3 per million | Rare, but not invisible; large enough to support scaled disease education |
| US MG prevalence | 37.0 per 100,000 | Confirms a meaningful diagnosed base for awareness and future franchise expansion |
| US MG incidence | 3.1 per 100,000 | New-patient flow exists; diagnosis dynamics still matter |
| MG work impairment | 30.0% overall work impairment | Patient burden is not abstract; functional loss is economically visible |
| MG activity impairment | 39.2% non-work activity impairment | Supports patient-journey and quality-of-life framing |
| US MG spend | \$5,567 PMPM | Baseline disease cost is already high before premium targeted therapies |
| MG acute-event spend | \$17,330 PMPM | Crisis / exacerbation economics justify earlier recognition and better control narratives |
| Exacerbation annual spend | \$43,734/year | Acute instability remains a major value drain |
| Post-crisis annual spend | \$173,956.99/year | High-severity MG is a very expensive health-system problem |
| Dianthus `gMG` Phase 2 size | n=65 | Early signal is meaningful but still relatively small and pre-registrational |
| Dianthus Phase 2 `gMG` effect | MG-ADL placebo-adjusted improvement 1.8 points at Week 13 | Scientifically encouraging, but not yet enough for outward value-led positioning |
| Internal franchise breadth | 3 active indications (`gMG`, `CIDP`, `MMN`) | Real franchise logic exists, not a single-asset illusion |
| Internal 2026 catalysts | 3 key catalysts (gMG Phase 3 start, CIDP interim, MMN topline) | 2026 is the franchise-shaping year |
| Internal long-range catalyst | 2H 2028 gMG topline | `gMG` remains the long-cycle value inflection point |
| Competitive `gMG` density | ~7-8 targeted brands in US, ~6-7 in EU depending market and timing | `gMG` is no longer a white-space launch |
| Competitive `CIDP` density | 1 EMA-approved targeted biologic already established | `CIDP` has moved from baseline to contested |
| Competitive `MMN` targeted approvals | 0 retrieved targeted non-Ig approvals | `MMN` remains the cleanest whitespace |

| Domain | Quantitative anchor | What it means strategically |
|---------------------------------------|--|--|
| Public annual biologic pricing signal | CAD 298k-447k for Vyvgart; CAD 523k-569k for Ultomiris; CAD 697k-710k for Soliris | Pricing / access friction will remain central to franchise success |
| EU supply signal | Immunoglobulin shortage expected through June 2026 | Makes `CIDP` / `MMN` treatment dependence more strategically relevant |
| Key external catalyst date | May 10, 2026 VYVGART seronegative `gMG` PDUFA | Could further strengthen the category leader before Dianthus enters registrational `gMG` execution |

2) What the Numbers Say About the Core Strategic Problem

The disease burden numbers are large enough to justify an awareness agenda, but the market structure numbers make it clear that **this cannot be a simplistic “there is a disease and few options” story.**

In `gMG`, the burden case is strong: **37.0 per 100,000 prevalence in the US, 30.0% work impairment, 39.2% activity impairment**, and acute-event spending that rises to **\$17,330 PMPM**. Those figures support a real unmet-need narrative. But that disease burden now sits inside a therapeutic landscape that already includes roughly **7-8 targeted brands in the US and 6-7 in Europe**, depending jurisdiction and timing. In other words, the burden is real, but the market is no longer early.

That combination changes the strategic task. The franchise cannot win by arguing that innovation is merely arriving. It has to show that **important unmet need persists despite therapeutic progress**. That is a more nuanced and more credible narrative.

The same logic does not apply equally across the franchise. In `CIDP`, the competitive picture is less crowded than `gMG`, but it is no longer pre-biologic. With **Vyvgart now EMA-authorized in `CIDP`**, the category has crossed an important threshold: biologic treatment is now part of the mainstream European reference frame. That means a future Dianthus `CIDP` story must be written against a market that already accepts targeted innovation, not against a market defined only by steroids and immunoglobulins.

`MMN` is different again. In the session’s evidence base, `MMN` remains the indication with the strongest white-space features: high functional burden, continued dependence on immunoglobulin, limited approved targeted alternatives, and now an external operational stressor in the form of the **EU immunoglobulin shortage**. That makes `MMN` the cleanest place for a franchise to argue that treatment pathways are still too fragile and too dependent on chronic supply-sensitive therapy.

So the numbers point to a simple franchise conclusion:

- **`gMG` is the proof market**
- **`CIDP` is the scale bridge**
- **`MMN` is the unmet-need white space**

3) Why the Franchise Story Works -- and Why It Cannot Be One-Size-Fits-All

The main structural advantage visible in the session is that Dianthus has a **single-asset, three-indication neuromuscular franchise** in motion. That matters because the company has **three active clinical programs** and **three meaningful 2026 catalysts**, while most competitors are either concentrated in `gMG` only or spread across the franchise in a less coherent way.

That is the positive side of the equation.

The limiting side is that the quantitative evidence maturity is not the same across the three diseases. The `gMG` program currently rests on a **65-patient Phase 2 study** with a **1.8-point placebo-adjusted MG-ADL improvement at Week 13**. That is directionally encouraging and strategically useful, but it is not yet the kind of evidence base that should dominate external franchise storytelling. The same is true even more strongly in `CIDP` and `MMN`, where the story is even earlier.

This is why the best franchise architecture is not a single mechanism-first slogan. It is a **three-layer system**:

1 One franchise thesis

Autoimmune neuromuscular diseases still create disproportionate burden because diagnosis, treatment dependence, and long-term control remain difficult.

2 One disease-family layer

Shared issues are delayed recognition, functional loss, care-fragmentation, and treatment burden.

3 Three indication-specific branches

`gMG` = persistent unmet need despite therapeutic progress
 `CIDP` = relapse / progression plus maintenance burden in a newly contested biologic category
 `MMN` = functional preservation plus dependence on immunoglobulin and limited alternatives

The numbers support this architecture because the disease-burden data are shared enough to justify a franchise, but the competitive-density data are different enough to require disease-specific adaptation.

4) What the Competitive Numbers Mean for the Awareness Plan

The competitive intelligence gathered in the session makes one issue especially important: **the awareness plan is competing not only against products, but against narrative systems already in market.**

From the session's evidence:

- **argenx** is the current franchise leader, with approved `gMG` and `CIDP` presence plus late-stage `MMN` and `CIDP` expansion.
- **J&J** is emerging as the most aggressive comparative-narrative challenger in `gMG`.
- **UCB** retains meaningful scientific presence through its dual `gMG` portfolio.

- **Sanofi** is a material `CIDP` watch item.
- **Amgen** is now a real `gMG` player after `Uplizna` approvals.

This matters because the awareness plan cannot assume an empty educational field. It is entering a space where the top competitors are already generating:

- registrational publications,
- comparative evidence,
- real-world analyses,
- congress scale,
- medical portals,
- patient-support infrastructure.

That means the campaign's success should not be judged by whether it becomes the loudest voice quickly. It should be judged by whether it becomes the **most credible, most focused, and most insight-rich voice in the right white spaces**.

Quantitatively, the strongest awareness territories are those where burden remains high but competitive narratives are still incomplete:

- diagnosis delay and pathway fragmentation,
- real-life treatment burden,
- crisis / relapse economics,
- continuity-of-care risk,
- function and daily living impact,
- treatment dependence in `CIDP` / `MMN`.

The least attractive territory is a broad, vague "innovation is coming" message, because the market data already show innovation is here.

5) EU5: The Numbers Argue Against a Single European Story

The EU5 layer changes the plan materially.

The session's evidence shows that Europe is not one simple access environment:

- **UK:** efgartigimod is not recommended for routine NHS use in antibody-positive `gMG`; `CIDP` appraisal work is still developing.
- **Germany:** a **nipocalimab `gMG` benefit assessment** is active with a near-term decision window.
- **France:** Rystiggo has an important clinical role but limited incremental-value language and specialist validation features.
- **Italy:** reimbursement and registry mechanics are active, showing practical access depends on implementation detail.

- **Spain:** national positioning work is still an important gate for practical use.

Add to that the **EU immunoglobulin shortage through June 2026**, and the conclusion is straightforward: the European franchise plan must be **country-modular**, not just EU-branded.

In practical terms, the numbers imply at least **three EU5 sub-stories**:

- 1 **Restrictive HTA markets** -- where value and positioning are more fragile
- 2 **Specialist-gated markets** -- where expert networks drive access
- 3 **Operational-access markets** -- where registries, pathways, and implementation mechanics matter

So the franchise narrative can be common, but the applied story has to diverge. A single EU deck would almost certainly be too blunt.

6) The Real Strategic Meaning of 2026

The session contains a very important planning signal: **2026 is a compression year**.

Internally, Dianthus has:

- **mid-2026:** planned `gMG` Phase 3 initiation
- **2H 2026:** `CIDP` interim responder analysis
- **2H 2026:** `MMN` topline

Externally, the field has:

- **May 10, 2026:** VYVGART seronegative `gMG` PDUFA
- **mid-2026:** German `gMG` access movement for nipocalimab
- **July 2026:** UK `CIDP` appraisal milestone
- **September 2026:** empasiprubart `MMN` Phase 3 primary completion estimate
- **H2 2026:** Sanofi `CIDP` readout guidance

This means 2026 is not a slow prelaunch year. It is a year in which the external category may move almost as fast as Dianthus's internal plan. That has two consequences.

First, the awareness platform has to be durable enough to survive external label expansion and competitive data releases. Second, the internal operating model has to be built to refresh quickly, because static narrative work done in Q2 2026 could be outdated by Q4 2026.

The numbers therefore argue for a **living narrative architecture**, not a one-time campaign concept.

7) What the Quantitative Data Suggests the Plan Should Optimize For

Based on the session's evidence, the plan should optimize for **five things**:

1. Disease-state authority, not product adjacency

Because claseprubart is still investigational across all three diseases, the campaign must win on burden, pathway clarity, and credibility. The burden numbers support this.

2. White-space selection, not generic awareness

The market-density numbers show `gMG` is crowded. White-space value is likely higher in:

- diagnosis delay,
- treatment burden,
- continuity of care,
- immunoglobulin dependence,
- cross-specialty recognition.

3. Franchise coherence with disease-specific execution

Three active indications justify a franchise platform. Different competitive densities require three tailored branches.

4. Country modularity in EU5

The access evidence does not support a one-size-fits-all European execution model.

5. Measurement discipline from the start

The internal MAPS framework is clear that awareness work should be tied to both **goal-based** and **impact-oriented** measures. The most relevant internal metrics from the session are:

- **stakeholder reach percentage**
- **digital content engagement rate**
- **omnichannel journey completion rate**
- **medical education impact score**
- **insight quality score**
- **insight-to-action conversion rate**
- **patient-reported outcome integration**

One useful internal benchmark already surfaced in the taxonomy: **omnichannel journey completion above 30%** indicates strong execution; **15-30%** is developing; **below 15%** suggests fragmented engagement.

That matters because the plan so far is not just a narrative exercise. It is a launch-readiness system. If it is not measurable, it will become a set of activities rather than a strategic asset.

8) Integrated Strategic Conclusion

If the session is read as a whole, the quantitative evidence leads to a coherent conclusion:

- The **burden case** is strong enough to justify franchise-led disease awareness.
- The **competitive case** is strong enough to rule out simplistic innovation messaging.
- The **franchise case** is strong enough to justify a common backbone across `gMG`, `CIDP`, and `MMN`.
- The **EU5 access case** is strong enough to require local adaptation.
- The **2026 catalyst map** is dense enough that the plan must be dynamic.

So the best synthesis is this:

Dianthus should build one franchise platform around autoimmune neuromuscular disease burden, treatment dependence, and the need for more durable and practical long-term control -- but it should deploy that platform as three distinct indication stories, refreshed continuously against a fast-moving competitive and EU5 access environment.

That is the point at which the numbers and the narrative align.

Quantitative Implications for the Plan So Far

| Strategic question | Quantitative answer from session | Implication |
|--|--|--|
| Is there enough unmet need to justify awareness? | Yes: burden, impairment, and cost are all high | Proceed |
| Is `gMG` a clean awareness white space? | No: high burden, but very crowded | Narrow the `gMG` awareness territory |
| Is `CIDP` still underdeveloped competitively? | Partly, but not fully: at least 1 targeted biologic now approved in Europe | Update older assumptions |
| Is `MMN` the cleanest whitespace? | Yes, based on limited targeted competition and Ig dependence | Elevate in franchise planning |
| Is EU5 one market? | No | Build country modules |
| Is 2026 a low-change period? | No: multiple major internal and external catalysts | Set rapid-refresh governance |
| Can one master narrative work? | Yes -- at the franchise level | Use one backbone |
| Can one execution story work? | No | Use indication- and market-specific variants |

VERIFIED FACTS vs INFERENCES

VERIFIED FACTS

- MG burden, work impairment, and cost burden are substantial.
- Claseprubart has active / planned programs in `gMG`, `CIDP`, and `MMN`.
- The current `gMG` market is crowded with targeted approved options.
- `CIDP` now has EMA-recognized targeted biologic innovation.
- The EU immunoglobulin shortage remains a live environmental factor.
- Multiple major competitive catalysts are clustered in 2026.

INFERENCES

- `MMN` is likely the most attractive white-space narrative territory.
- The franchise will perform better if built around disease burden and treatment dependence rather than a uniform biology-first story.
- EU5 local adaptation is not optional; it is structurally necessary.
- The campaign's real differentiator will be credibility and relevance, not sheer share of voice.

NEEDS VERIFICATION

- Country-specific reimbursement depth for each competitor across EU5.
- Publicly retrievable patent-expiry windows relevant to the next 12-24 months.
- Competitor digital engagement volume in a standardized apples-to-apples way.

Notes

- This is an **extended narrative synthesis**, not a tactical campaign blueprint.
- Quantitative anchors are limited to data already retrieved and validated during the session.
- No investigational efficacy claim here should be read as a promotional statement.

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Message 10: sAimone Response

Dynamic Stakeholder Ecosystem Mapping

Scope: Dianthus / claseprubart franchise context across `gMG`, `CIDP`, and `MMN` **Use case:** awareness campaign + franchise narrative architecture **Validation date:** March 18, 2026

Executive Snapshot

- The stakeholder ecosystem is **not one network**; it is a **stacked ecosystem** with three overlapping communities: `gMG`, `CIDP/MMN`, and rare-disease policy / advocacy.
- The most influential stakeholders for this phase are **neuromuscular experts / centers of excellence, patient advocacy organizations, and disease-specific scientific societies**.
- The highest-interest stakeholders are **patients / carers, advocacy groups, and specialist clinicians**; the highest-formal-influence stakeholders are **guideline voices, HTA bodies, and regulators**, although some of those are lower-interest for a pure awareness campaign.
- From an awareness perspective, **patient organizations and specialist experts are the fastest route to credibility**; from a franchise perspective, **registry owners, societies, and guideline-linked experts are the fastest route to durable legitimacy**.
- `gMG` has the most organized named advocacy footprint right now, led by **MGFA, Myaware**, and the broader **MG Alliance** ecosystem.
- `CIDP/MMN` is structurally different: the most important ecosystem anchor is the **GBS/CIDP Foundation International** and related European / national affiliates.
- The **EU immunoglobulin shortage through June 2026** materially increases the relevance of pharmacists, infusion infrastructure, supply continuity stakeholders, and `CIDP/MMN` advocacy groups.
- The ecosystem is dynamic because influence shifts over time: **patients and experts dominate now**, while **payers / HTA / policy stakeholders become more important as the franchise moves closer to launch and access discussions**.
- The strongest collaboration opportunities are **disease education, diagnostic odyssey mapping, registry / natural-history partnerships, specialist referral pathway work, and patient-journey evidence generation**.
- The strongest advocacy potential sits with **patient organizations, KOLs / COEs, guideline committee members, and digital opinion leaders**, but each plays a different advocacy role.
- The biggest ecosystem risk is trying to activate all stakeholders equally; the network is too dense, and rare-disease communities have limited bandwidth.
- The best operating model is a **hub-and-spoke approach**: advocacy groups + COEs + societies as the hub, community neurology / referral networks / digital communities as the amplification spokes.

1) Ecosystem Logic

Core stakeholder thesis

For this project, the ecosystem is best understood as **five interacting clusters**:

1 Specialist care cluster

Neuromuscular neurologists, MG / neuropathy experts, COEs, investigators, specialist nurses, pharmacists

2 Patient and advocacy cluster

Patients, carers, disease foundations, support groups, digital communities, rare-disease coalitions

3 Scientific legitimacy cluster

Professional societies, guideline committee members, congress faculty, registry owners, researchers

4 Access and system cluster

HTA bodies, public / private payers, hospital formulary / pharmacy leadership, medical directors

5 Internal orchestration cluster

Medical affairs, patient advocacy, medical communications, market access, regulatory, clinical development

The campaign and franchise narrative succeed only if these five clusters are aligned enough to produce **consistent disease understanding**, while still respecting the fact that each cluster wants something different.

2) Influence / Interest Matrix

Scoring key: 1 = low, 5 = very high. Scores below are **analytical synthesis scores** based on the current session context, not externally published scores.

| Stakeholder group | Examples / anchors | Influence | Interest | Current relevance | Advocacy potential | Why they matter now |
|--|--|-----------|----------|-------------------|--------------------|--|
| Neuromuscular KOLs / COEs | MG specialist clinics, CIDP / MMN referral centers, congress faculty | 5 | 4 | 5 | 4 | Set clinical narrative, referral patterns, trial feasibility, congress visibility |
| Patient advocacy organizations -- MG | MGFA, Myaware, MG Alliance members | 4 | 5 | 5 | 5 | Highest-trust gateway for patient burden, diagnosis, awareness, and lived experience |
| Patient advocacy organizations -- CIDP / MMN | GBS/CIDP Foundation International, GBS/CIDP Organisation Europe | 4 | 5 | 5 | 5 | Central to CIDP / MMN white-space credibility and patient-community access |
| Guideline / society influencers | PNS, AANEM, EAN-linked experts, guideline committee members | 5 | 3 | 4 | 4 | Convert awareness and evidence into field-wide legitimacy |

| Stakeholder group | Examples / anchors | Influence | Interest | Current relevance | Advocacy potential | Why they matter now |
|--|---|-----------|-----------------|-------------------|--------------------|---|
| Clinical investigators / academic researchers | Trial investigators, registry stewards, natural-history leads | 4 | 4 | 5 | 3 | Bridge awareness, evidence generation, and future scientific platform |
| Community neurologists / referrers | General neurology, neuro-ophthalmology, neuromuscular referrers | 4 | 3 | 4 | 2 | Critical for recognition and earlier diagnosis, especially in `gMG` |
| Specialist nurses / pharmacists / infusion teams | Myasthenia nurses, infusion pharmacists, immunoglobulin logistics teams | 3 | 4 | 4 | 3 | Highly relevant to treatment-burden and continuity-of-care narratives |
| Digital opinion leaders / patient creators | Patient educators, online rare-disease advocates | 3 | 5 | 4 | 4 | Efficient amplifiers if engaged carefully and authentically |
| Registry owners / data partners | UKMyDb, patient registries, outcomes databases | 4 | 4 | 4 | 3 | High value for patient journey, burden, and natural-history evidence |
| Rare-disease umbrella groups | NORD, Rare Disease UK, national alliances | 3 | 4 | 3 | 4 | Strong for policy and broad awareness, but less disease-specific |
| HTA bodies / payers | NICE, G-BA, HAS, AIFA, AEMPS / REvalMed, medical directors | 5 | 2 now / 4 later | 3 | 2 | Limited relevance for broad awareness now; major relevance later for access narrative |
| Regulators | FDA, EMA, MHRA, EC processes | 5 | 1 now / 3 later | 2 | 1 | High formal influence but low practical role in awareness execution |
| Internal cross-functional leads | Medical, patient advocacy, access, regulatory, clinical, med comms | 5 | 5 | 5 | N/A | The internal network determines whether the external network experiences coherence or fragmentation |

Matrix interpretation

- **High influence / high interest:** KOLs / COEs, patient advocacy organizations, internal leadership
- **High influence / lower current interest:** payers, HTA, regulators
- **High interest / moderate influence:** patients, carers, digital communities, local support groups
- **Strategic bridge actors:** societies, investigators, registries, specialist nurses / pharmacists

3) Dynamic Engagement Journeys

A. Neuromuscular experts / COEs

| Journey stage | Current state | Desired state | Value exchange | Watch-outs |
|---------------|--|---|---|---|
| Awareness | Category aware, but time-constrained and exposed to heavy competitor noise | See Dianthus ecosystem as credible, disease-first, and scientifically serious | High-quality burden / pathway / evidence dialogue | Low tolerance for superficial disease messaging |
| Engagement | Periodic congress / MSL interactions | Ongoing bidirectional scientific exchange | Insight capture, pathway mapping, unmet-need refinement | Compliance / pre-promotional boundaries |
| Collaboration | Ad hoc content input | Structured role in education, referral pathway, registry, advisory, evidence generation | Scientific legitimacy and signal detection | Overburden risk in rare disease |
| Advocacy | Informal peer influence | Willingness to amplify disease-state gaps and future care needs | Community leadership, congress presence, referral influence | Must be evidence-grounded, not sponsor-scripted |

Implication: these stakeholders are the **highest-leverage hub actors** in the whole ecosystem.

B. Patient advocacy organizations

| Journey stage | Current state | Desired state | Value exchange | Watch-outs |
|---------------|--|---|--|---|
| Awareness | High disease familiarity; variable sponsor trust | View Dianthus as authentic, patient-focused, and non-extractive | Listening, burden validation, resource support | Community skepticism if engagement feels product-led |
| Engagement | Event-based interactions and shared awareness spaces | Regular structured dialogue | Patient journey mapping, diagnosis pain points, language testing | Need clear role boundaries and transparency |
| Collaboration | Local education or awareness support | Co-created plain-language disease materials, surveys, advisory input, registry / pathway partnerships | High credibility and reach | Must not overload limited staff and volunteer bandwidth |
| Advocacy | Existing community advocacy already active | Independent amplification of disease-state priorities | Diagnosis, access, continuity of care, invisible burden | Advocacy must remain theirs, not company-authored |

Implication: advocacy groups are the **highest-trust amplifiers**, especially for awareness and plain-language narrative validation.

C. Community neurology / referrers

| Journey stage | Current state | Desired state | Value exchange | Watch-outs |
|---------------|--|---|--|--|
| Awareness | Partial recognition; lower specialty immersion | Faster recognition and referral of probable disease | Simplified disease / referral education | Must be practical, not specialist-jargon heavy |
| Engagement | Low-touch and fragmented | Reached through layered omnichannel education | Practical algorithms, red flags, referral triggers | Engagement fatigue, channel fragmentation |
| Collaboration | Limited | Referral pathway improvement and local education | Better patient flow and earlier specialist access | Requires local adaptation |
| Advocacy | Low | Moderate | Can amplify awareness indirectly through clinical behavior | Usually not public advocates |

Implication: community neurology is a **scale multiplier**, but not the primary narrative originator.

D. Payers / HTA / policy stakeholders

| Journey stage | Current state | Desired state | Value exchange | Watch-outs |
|---------------|---|--|--|--|
| Awareness | Interested mainly in burden, utilization, and access consequences | Understand disease burden and treatment-pathway stress early | Burden framing, pathway economics, continuity-of-care issues | Too-early access engagement can distort awareness priorities |
| Engagement | Limited at awareness stage | Evidence-oriented, later-stage dialogue | HEOR, registries, RWE, burden | Avoid premature value claims |
| Collaboration | Low now | Moderate later | Evidence design and real-world endpoints | Timing sensitivity |
| Advocacy | Low in public disease awareness | Moderate in policy environments | Can influence system-level recognition of burden | Usually not public-facing advocates |

Implication: high formal influence, but **later-wave stakeholders** for this project.

E. Digital opinion leaders / online communities

| Journey stage | Current state | Desired state | Value exchange | Watch-outs |
|---------------|--|--|---|---|
| Awareness | High engagement, high lived-experience value | Become a listening and amplification layer | Community language, sentiment, unmet needs | Misinformation, moderation variability, reputational risk |
| Engagement | Informal and fast-moving | Structured but light-touch monitoring and partnership | Reach and rapid feedback | Over-commercialization risk |
| Collaboration | Selective | Awareness moments, digital education, social listening | Real-time insight on language and pain points | Needs strong governance |
| Advocacy | High if authentic | High | Powerful amplification channel | Difficult to control; authenticity critical |

Implication: digital communities are **high-interest amplifiers**, but not substitutes for formal advocacy or scientific leadership.

4) Collaboration Opportunity Map

| Opportunity | Best-fit stakeholders | Strategic purpose | Advocacy potential | Confidence |
|--|---|---|------------------------|------------|
| Diagnostic odyssey mapping | MGFA, Myaware, GBS/CIDP Foundation, COEs, referral neurologists | Sharpen disease-state education and referral narrative | High | High |
| Patient journey evidence generation | Advocacy groups, registries, academic researchers | Create franchise-consistent burden evidence | High | High |
| Plain-language disease education | Patient organizations, specialist nurses, digital patient communities | Improve awareness and message accessibility | High | High |
| Referral pathway optimization | COEs, community neurologists, hospital department heads, pharmacists | Reduce delay and improve specialist routing | Moderate | High |
| Registry / natural history collaboration | UKMyDb, registry owners, academic leads, advocacy groups | Build durable evidence layer for franchise | Moderate to high | High |
| Congress / scientific session alignment | PNS, AANEM, MGFA Scientific Session, KOLs | Increase scientific visibility and stakeholder alignment | Moderate | High |
| Specialist nurse / infusion burden mapping | Nurses, pharmacists, infusion services, patient orgs | Particularly relevant for `CIDP` / `MMN` continuity-of-care narrative | Moderate | High |
| Policy / awareness month activation | MG Awareness Month networks, MMN awareness activities, rare-disease umbrella groups | Public-facing visibility and coalition building | High | Moderate |
| HEOR / access burden framing | HTA agencies, payer medical directors, health economists | Later-stage access preparation | Low now / higher later | High |

Most attractive collaboration themes now

- 1 **Diagnosis and referral**
- 2 **Patient journey / lived burden**
- 3 **Continuity of care**
- 4 **Registry / natural history**
- 5 **Plain-language education**

5) Advocacy Potential Ladder

| Advocacy tier | Stakeholders | Why they are here |
|--|--|--|
| Tier A -- Primary advocates | MGFA, Myaware, GBS/CIDP Foundation International, major COE KOLs, guideline-linked experts | Highest trust + strongest ability to influence disease understanding |
| Tier B -- High-value amplifiers | Specialist nurses, pharmacists, digital opinion leaders, registry investigators, society faculty | Strong multiplier effect but usually need a validated narrative first |
| Tier C -- System shapers | HTA bodies, payers, policy coalitions, rare-disease umbrella organizations | High system influence, lower public advocacy relevance at the current campaign stage |
| Tier D -- Monitoring / opportunistic engagement | Media, general health influencers, broader hospital administrators | May matter later, but lower immediate franchise value |

Advocacy readout by indication

- **gMG**: strongest named advocacy infrastructure
- **CIDP**: advocacy strength is good, but more functionally tied to support, education, and pathway navigation
- **MMN**: strongest white-space advocacy potential because the disease remains under-recognized and highly dependent on limited treatment pathways

6) Ecosystem Hubs and Influence Cascades

Primary ecosystem hubs

| Hub | Why it is a hub | Downstream influence |
|--|---|---|
| Patient advocacy organizations | Trust, lived experience, event infrastructure, plain-language credibility | Patients, carers, policymakers, media, local support groups |
| COEs / KOLs | Clinical authority and referral legitimacy | Community neurologists, guideline work, congresses, investigators |
| Scientific societies / congresses | Structured legitimacy and dissemination | Experts, trainees, allied HCPs, publication agendas |
| Registries / data owners | Quantify burden and outcomes | HTA, publications, evidence generation, policy |
| Internal medical / patient advocacy leadership | Cross-functional coherence | Every external touchpoint |

Most important influence cascades

- 1 **Advocacy -> patient language -> plain-language narrative -> community trust**
- 2 **COE / KOL -> society / congress visibility -> broader HCP legitimacy**
- 3 **Registry / natural history data -> publications / HEOR -> payer / HTA relevance**
- 4 **Specialist nurses / pharmacists -> treatment burden insight -> continuity-of-care narrative**
- 5 **Community neurology -> referral behavior -> earlier diagnosis**

7) Dynamic Prioritization by Time Horizon

| Time horizon | Primary stakeholders | Secondary stakeholders | Main objective |
|---------------------------------|---|--|--|
| Now to 2H 2026 | Patient advocacy groups, COEs, KOLs, registries, community neurologists | Digital communities, specialist nurses, pharmacists | Build disease authority and gather insight |
| 2H 2026 to 2H 2027 | Societies, guideline influencers, broader HCP education ecosystem | Rare-disease umbrella organizations, regional affiliates | Expand legitimate reach and shape the professional narrative |
| 2H 2027 to 2H 2028 | Payers, HTA, access experts, policy stakeholders | Hospital systems, formulary actors | Translate burden narrative into access relevance |
| Post-readout / prelaunch | All above, in coordinated sequence | Broader market-access and commercialization interfaces | Convert ecosystem trust into launch readiness |

Dynamic conclusion

The ecosystem should be managed as a **sequenced network**, not a flat stakeholder list.

8) Influence / Interest Matrix -- Simplified Quadrant View

| Quadrant | Stakeholders | Practical implication |
|---|--|---|
| Manage closely (high influence / high interest) | COEs, KOLs, advocacy organizations, internal medical leadership | Highest-priority relationship infrastructure |
| Keep strategically aligned (high influence / lower current interest) | HTA bodies, payers, regulators, policy actors | Engage selectively and mostly through evidence / burden framing |
| Mobilize and enable (lower influence / high interest) | Patients, carers, support groups, digital communities | Strong awareness and amplification role |
| Monitor / activate selectively (lower influence / lower interest) | General media, non-specialist administrators, broad public-health actors | Use only when campaign phase and evidence maturity justify |

9) Strategic Interpretation

The stakeholder map shows that the current project should not be run as a typical “medical stakeholder engagement plan.” It should be run as a **community-centered franchise ecosystem strategy**.

The most important lesson is that **trust and influence are not held by the same actors**.

- Trust sits most strongly with **patient organizations and expert clinics**.
- Formal influence sits most strongly with **guideline, payer, and regulatory actors**.
- Amplification sits most strongly with **digital communities and society platforms**.

The campaign and franchise narrative will work best if those roles are respected rather than blurred.

That leads to one practical conclusion: the first objective is **not maximum reach**. It is **correct network activation**.

VERIFIED FACTS vs INFERENCES

VERIFIED FACTS

- The stakeholder taxonomy identifies healthcare professionals, external experts, patients / carers, market access payers, regulators, societies / associations, digital health, and academia / research as core stakeholder categories.
- Rare-disease MAPS guidance explicitly elevates patient organizations, clinicians, policy makers, and payers as key external groups.
- MGFA is a leading MG advocacy organization with a 2026 National Patient Conference and 2026 Scientific Session.
- Myaware is the major UK myasthenia charity and cites approximately **20,000** people living with myasthenia in the UK.
- The GBS/CIDP Foundation International explicitly supports **GBS, CIDP, MMN, and related conditions** and remains a core advocacy anchor.
- The Peripheral Nerve Society has published / hosted CIDP guideline work and is actively preparing 2026 programming.
- The EMA immunoglobulin shortage remains active through **June 2026**, increasing the relevance of `CIDP/MMN` treatment continuity stakeholders.

INFERENCES

- Patient organizations and COEs are the highest-leverage hub actors for the current awareness / franchise phase.
- `MMN` offers disproportionate advocacy whitespace because the disease remains under-recognized and highly treatment-dependent.
- Payers and HTA bodies are strategically important but should be sequenced after the disease-awareness and burden infrastructure is stronger.
- The most effective ecosystem model is hub-and-spoke, not equal-weight engagement.

NEEDS VERIFICATION

- Country-by-country named KOL / COE lists for EU5 and US.
- Exact chapter distribution and event density for all advocacy partners in each priority market.
- Disease-specific digital influence maps for MG vs CIDP / MMN communities.

Notes

- This is a **dynamic stakeholder ecosystem map**, not a detailed engagement plan or RACI.
- Named organizations are included as current public ecosystem anchors, not as endorsed partners.
- “Advocacy potential” here refers to likely disease-state amplification and community influence, not promotional advocacy.

References (accessed March 18, 2026)

Internal knowledge sources

- stakeholder_taxonomy_v2.json -- stakeholder categories, relationship graph logic, temporal factors, region hierarchy
- pillars_v2.json -- stakeholder-linked strategic pillars, evidence interpretation, patient advocacy, digital omnichannel, field medical
- tactics_taxonomy_v2.json -- tactic families, congress / education / digital / patient advocacy / scientific exchange pathways
- role_taxonomy_v1.json and role_taxonomy_v2.json -- global stakeholder map, cross-functional alignment narrative, launch governance expectations
- 00-MAPS-WP-Rare-Diseases-FINAL.pdf -- rare disease stakeholder groups, diagnosis awareness, patient organization priority, launch nuances
- external_scientific_engageme.pdf -- widening field medical audiences and digital / payer / patient-group engagement
- maps_launch_excellence_s_l11.pdf -- stakeholder insights, regional adaptation, medical launch planning, measurement hierarchy
- scientific-communications-st.pdf -- audience engagement and platform workshop structure
- pricing_market_access_v2.json -- stakeholder IDs and access / HTA-linked entities

External validation sources

- Myasthenia Gravis Foundation of America (MGFA) home page. <https://myasthenia.org/>
- 2026 MGFA National Patient Conference. <https://myasthenia.org/events/2026-mgfa-national-patient-conference/>
- 2026 MGFA Scientific Session. <https://myasthenia.org/events/2026-scientific-session/>
- MGFA events calendar. <https://myasthenia.org/mgfa-events-webinars/events/>
- The MG Alliance. <https://themgalliance.org/>
- Conquer Myasthenia Gravis. <https://myastheniagravis.org/>
- Myaware (UK). <https://www.myaware.org/>
- Myaware UK NHS listing. <https://www.nhs.uk/services/service-directory/myaware-%E2%80%93-fighting-myasthenia-together/N10973377>
- UK Myasthenia Database (UKMyDb), University of Oxford / funded by Myaware.

- <https://www.ndcn.ox.ac.uk/research/myasthenia-gravis-research-group/ukmydb>
- GBS/CIDP Foundation International home. <https://www.gbs-cidp.org/>
- GBS/CIDP Foundation International mission and vision. <https://www.gbs-cidp.org/about/mission/>
- GBS/CIDP Organisation Europe informational booklets.
<https://eu.gbs-cidp.org/resources/informational-booklets/>
- Peripheral Nerve Society guidelines page. <https://pnsociety.com/resources/guidelines/>
- 2026 PNS call for mini-symposia. <https://pnsociety.com/event/2026-call-for-mini-symposia/>
- EMA human normal immunoglobulins shortage page.
<https://www.ema.europa.eu/en/medicines/human/shortages/human-normal-immunoglobulins>
- G-BA nipocalimab Nutzenbewertung in myasthenia gravis.
<https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1300/>

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Message 11: User

i also need a payer analysis please

Message 12: sAimone Response

Payer Analysis

Scope assumed from the session: Dianthus / claseprubart franchise across `gMG`, `CIDP`, and `MMN`, with emphasis on **EU5 + US signals** **Perspective:** awareness campaign + franchise narrative + future access readiness **Validation date:** **March 18, 2026**

Executive Summary

- The payer story is **not the same** across `gMG`, `CIDP`, and `MMN`. These are three related but economically distinct access environments.
- In `gMG`, payers are now looking at a **crowded premium biologic category**. The core payer question is no longer whether targeted therapies matter; it is **which patients justify which high-cost therapy, at what point in line of treatment, and against which comparator**.
- In `CIDP`, the payer environment has changed materially because **Vyvgart now has an EMA-recognized `CIDP` indication** and formal HTA activity is underway in Europe. `CIDP` is no longer a pure immunoglobulin-maintenance category.
- In `MMN`, the payer environment remains the least transformed commercially: **immunoglobulin remains the practical standard of care**, and the main payer concern is continuity, supply, and chronic utilization rather than biologic class sequencing.
- A major cross-indication payer variable is the **ongoing EU immunoglobulin shortage expected through June 2026**, which raises the salience of treatment continuity and supply resilience, especially for `CIDP` and `MMN`.
- The strongest public economic anchor from the session remains `gMG` burden: **\$5,567 PMPM** average cost in US claims, rising to **\$17,330 PMPM** in patients with exacerbation / crisis, with post-crisis annual costs reaching **\$173,956.99**.
- Public pricing anchors confirm the challenge: CADTH-listed annual costs were approximately **CAD 298k-447k** for Vyvgart, **CAD 523k-569k** for Ultomiris, and **CAD 697k-710k** for Soliris.
- UK payer access remains restrictive in `gMG`: NICE states efgartigimod is **not normally available on the NHS** for antibody-positive `gMG`.
- Germany is now highly relevant for forward planning: `gMG` benefit assessment for **nipocalimab** is active, and a `CIDP` AMNOG process for **efgartigimod** has already reached resolution.
- France remains highly comparator-sensitive: HAS explicitly noted the absence of comparison with **rituximab**, which is commonly used off-label in practice, when assessing Rystiggo.
- Italy and Spain show that access is often shaped not just by label and HTA logic, but by **registries, therapeutic positioning reports, and administrative implementation criteria**.
- In the US, coverage remains **plan-fragmented**. Route of administration matters because it can change whether a therapy sits under the **medical benefit / Part B** or **pharmacy benefit / Part D**, which materially changes payer behavior.
- For Dianthus, the future payer narrative should be built less around “novel mechanism” and more around **who still has burden, where current pathways remain inefficient, and where chronic dependence on burdensome therapy remains economically and operationally unsatisfactory**.
- The strongest payer white-space is likely `MMN`, followed by selected `CIDP` subsegments; `gMG` is the most competitive and comparator-sensitive environment.
- From an awareness perspective, payer analysis does not change the external disease-state campaign directly, but it should materially change **which burden themes, evidence gaps, and outcomes are prioritized now**.

1) Payer Archetype Map

| Market | Primary payer / HTA archetype | Current practical payer posture | Relevance to franchise |
|---------|---|---|------------------------|
| US | Fragmented commercial + Medicare / Medicaid | Coverage plan-specific; route / site-of-care strongly influence access pathway | High |
| Germany | AMNOG / G-BA benefit assessment | Fast, formal, evidence-heavy, comparator-sensitive | Very high |
| France | HAS / CT value and reimbursement logic | High emphasis on comparator, SMR / ASMR, specialist use context | Very high |
| Italy | AIFA reimbursement + registry model | Access often shaped by registries and prescribing criteria | High |
| Spain | AEMPS / IPT / REvalMed | Positioning report logic and staged implementation matter | High |
| UK | NICE cost-effectiveness gate | Restrictive in high-cost rare-neuro settings when value case is weak or uncertain | Very high |

Payer interpretation

The franchise needs **one payer evidence backbone** but **six practical payer stories**: US plus EU5 country modules.

2) Indication-by-Indication Payer Readout

A. `gMG`

| Payer dimension | Current reality | Implication |
|--------------------------------|---|--|
| Category maturity | Multiple premium targeted therapies now available across FcRn, complement, and B-cell depletion | `gMG` is now a comparator-heavy market |
| Clinical evidence expectations | Payers want clearer differentiation beyond “improves MG-ADL” because several assets can now claim meaningful functional benefit | Incremental value narrative must be sharper |
| Comparator pressure | France explicitly flagged lack of comparison vs rituximab for Rystiggo; UK rejected efgartigimod on NHS value grounds | Off-label real-world comparators matter, even when not label comparators |
| Utilization management | Public payer policies in the US show prior authorization, antibody-status specificity, refractory / prior-treatment history criteria, and benefit-channel rules | Access is likely to remain highly managed |
| Economic tension | High disease burden is real, but biologic annual cost remains very high | Budget impact remains central |

| Payer dimension | Current reality | Implication |
|-----------------------|---|--|
| Narrative consequence | Payer story in `gMG` must be “residual unmet need despite multiple options” | Simple innovation narrative will not suffice |

`gMG` payer conclusion

`gMG` is the hardest payer market in the franchise because it combines:

- high unmet need,
- multiple approved premium therapies,
- strong off-label practice history,
- increasing comparator expectations,
- and visible HTA skepticism in parts of Europe.

B. `CIDP`

| Payer dimension | Current reality | Implication |
|---------------------------|---|---|
| Category maturity | `CIDP` has now crossed into the targeted-biologic era in Europe with Vyvgart | Payers must now reframe `CIDP` beyond Ig / steroid maintenance only |
| Formal HTA activity | Germany completed AMNOG resolution on efgartigimod in January 2026; France and Italy have active public documentation; UK appraisal work is ongoing | `CIDP` access will evolve rapidly in 2026 |
| Comparator baseline | Corticosteroids, IVIG / SCIg, plasma exchange, and maintenance immunoglobulin remain the real-world economic benchmark | Any new entrant must prove why it deserves a place against established maintenance pathways |
| Route / service economics | Home SCIg and maintenance immunoglobulin already offer outpatient / home-based logic in some settings | Convenience alone will not be enough without stronger value framing |
| Supply stress | EU Ig shortage through June 2026 makes continuity-of-care and dependency on Ig a stronger payer issue | Opens space for “pathway resilience” and “treatment continuity” arguments |
| Narrative consequence | `CIDP` payer narrative should focus on relapse prevention, maintenance burden, and resource intensity of chronic treatment dependence | Strongest near-term payer opportunity after `MMN` |

`CIDP` payer conclusion

`CIDP` is no longer a clean white space, but it is still a **highly contestable market**. Payers are likely to ask:

- who truly needs a targeted alternative,
- what happens to chronic immunoglobulin use,

- whether relapse reduction is meaningful enough,
- and whether real-world maintenance burden can be reduced.

C. `MMN`

| Payer dimension | Current reality | Implication |
|-----------------------|--|---|
| Category maturity | No new targeted approved competitive standard retrieved in this pass; IVIG remains core | `MMN` remains payer-defined by chronic supportive immunomodulation |
| Standard of care | EMA materials confirm immunoglobulin products retain MMN indication and role | Current payer pathways are familiar but supply-dependent |
| Budget logic | Rare population constrains total budget impact, but chronic treatment dependence creates ongoing cost exposure | Smaller population, but persistent maintenance economics |
| Operational risk | Ig shortage is a highly relevant external stressor | Continuity and supply security become part of the payer problem statement |
| Competitive pressure | Empasiprubart orphan designation and development mean this will not stay static | White space exists, but not indefinitely |
| Narrative consequence | `MMN` is the cleanest access story for the franchise: functional dependence + limited alternatives + chronic Ig reliance | Strongest payer white-space signal |

`MMN` payer conclusion

If the franchise needs one indication where the payer narrative is still relatively under-occupied, it is `MMN`.

3) Public Access / HTA Signals by Market

| Market | Public signal retrieved | What it means |
|---------|---|--|
| UK | NICE states efgartigimod is not normally available on the NHS in antibody-positive `gMG` | UK remains highly value-constrained in `gMG` |
| Germany | Nipocalimab `gMG` AMNOG process began January 2026; resolution expected mid-June 2026 | German `gMG` payer environment remains dynamic |
| Germany | Efgartigimod `CIDP` AMNOG process resolved January 22, 2026 | `CIDP` is now fully in German reimbursement logic |
| France | HAS considered Rystiggo important only as add-on to standard therapy in symptomatic `AChR` + / `MuSK` + disease and criticized lack of rituximab comparison | France is comparator- and positioning-sensitive |
| France | HAS updated Ultomiris early-access materials in `gMG` | Access logic is evolving and specialist-context driven |
| Italy | AIFA approved reimbursement actions in `gMG`; VYVGART registry modifications show implementation detail matters | Registry design materially shapes practical access |
| Italy | AIFA documents show CIDP efgartigimod reimbursement / determination activity | `CIDP` is entering formal payer implementation |
| Spain | IPT exists for Rystiggo in `gMG` | Spain uses positioning reports as a key access gate |
| Spain | AEMPS / REvalMed and bulletin processes continue to signal staged access evolution | National positioning matters as much as EMA label |
| EU-wide | EMA continues to list a shortage of human normal immunoglobulins through June 2026 | Payers may become more attentive to Ig-dependent pathway fragility |

4) US Payer Analysis

What is different about the US

The US is less centralized, so there is no single “payer decision.” Instead, public signals indicate three practical truths:

1 Route of administration changes the payer problem

Infused / provider-administered agents often flow through the **medical benefit / Part B**, while self-administered products can shift toward **pharmacy benefit / Part D** or commercial pharmacy pathways.

2 Coverage is highly policy-based

Public payer / commercial policy documents retrieved in this pass show the use of:

- prior authorization,
- antibody-status criteria,
- prior-treatment or refractory criteria,
- dosing / frequency rules,
- and continuation-of-therapy checks.

3 Site-of-care and benefit-channel economics matter

A payer may react differently to an IV infusion, physician-office administration, hospital outpatient infusion, self-injection, or specialty pharmacy distribution, even if the clinical claim is similar.

US payer implication for the franchise

- `gMG`: highly managed access with route-driven benefit complexity
- `CIDP`: likely to become increasingly managed as targeted entrants expand
- `MMN`: if a targeted entrant arrives, payer questions will likely center on whether it reduces or replaces chronic Ig dependence

5) Quantitative Payer Anchors

| Quantitative anchor | Value | Payer read-through |
|--|--|---|
| US `gMG` average spend | \$5,567 PMPM | Baseline burden is already material |
| US `gMG` exacerbation / crisis spend | \$17,330 PMPM | Acute instability is extremely expensive |
| Post-crisis annual cost | \$173,956.99 | Severe events create a strong economic rationale for better control |
| Vyvgart annual public price signal | CAD 298k-447k | Premium biologic threshold |
| Ultomiris annual public price signal | CAD 523k-569k | Higher-cost premium comparator |
| Soliris annual public price signal | CAD 697k-710k | Legacy premium ceiling |
| EU Ig shortage duration | Through June 2026 | Makes continuity / substitution / dependency more payer-relevant |
| Germany nipocalimab `gMG` process | Began 01 Jan 2026 , decision expected mid-Jun 2026 | Near-term change risk in `gMG` access environment |
| Germany efgartigimod `CIDP` resolution | 22 Jan 2026 | Confirms `CIDP` is now a live payer category in Germany |

Quantitative interpretation

The payer problem is simple:

- disease burden is costly enough to justify intervention,
- but treatment prices are high enough to force restriction,
- so winning requires a **narrower and more evidence-rich value story** than broad disease burden alone.

6) What Payers Are Most Likely to Reward

| Value driver | `gMG` | `CIDP` | `MMN` |
|--|-----------|------------------|-----------|
| Clear subgroup identification | High | Moderate | Moderate |
| Reduced relapse / exacerbation | High | High | Moderate |
| Functional benefit / disability preservation | High | High | High |
| Lower chronic treatment burden | High | High | Very high |
| Reduced dependence on immunoglobulin | Moderate | Very high | Very high |
| Site-of-care simplification | High | Moderate to high | Moderate |
| Strong comparator logic | Very high | High | Moderate |
| PRO / QoL evidence | High | High | High |
| Real-world durability | Very high | Very high | High |
| Budget predictability | High | High | Moderate |

Key payer message by indication

- **`gMG`**: Which patients, why this therapy, why now, versus what else?
- **`CIDP`**: Can chronic maintenance burden and relapse risk be reduced in a way that is clinically and operationally meaningful?
- **`MMN`**: Can treatment dependence on scarce / burdensome immunoglobulin pathways be reduced without loss of function?

7) What This Means for the Awareness Campaign and Franchise Narrative

The payer analysis should not turn the awareness campaign into a payer campaign. But it should shape **which disease-state themes are emphasized now**, because those themes become the foundation of later value arguments.

Themes the campaign should emphasize because payers will later care about them

- diagnosis delay and misrecognition
- functional burden and disability
- relapse / crisis / deterioration consequences
- continuity-of-care risk
- chronic treatment burden
- healthcare resource use
- patient and caregiver burden
- dependence on complex or supply-sensitive treatment pathways

Themes to avoid over-emphasizing at this stage

- broad mechanism-led superiority narratives
- generic “innovation” language without pathway context
- value claims that imply future access conclusions before evidence maturity

Strategic translation

A good awareness campaign can quietly strengthen the future payer narrative if it helps establish:

- 1 the size of the burden,
- 2 the inefficiency of current pathways,
- 3 the cost of instability,
- 4 and the importance of treatment fit and continuity.

8) Risk Assessment for Payer Readiness

| Risk | Why it matters | Current severity |
|---|---|------------------|
| `gMG` access crowding | Too many premium comparators with overlapping benefit claims | High |
| Weak comparator strategy | France already shows that off-label / practical comparators influence judgments | High |
| EU5 heterogeneity | One European market-access narrative will fail | High |
| Insufficient neuropathy-specific burden data | Especially relevant for `MMN` and `CIDP` if future targeted differentiation depends on pathway burden | Moderate to high |
| Over-reliance on mechanism novelty | Payers reimburse outcomes, not novelty alone | High |
| Underestimating route / channel economics in US | Benefit design may materially affect uptake | Moderate to high |
| Ig shortage normalization risk | If shortage resolves quickly, continuity narrative may weaken; if it extends, urgency increases | Moderate |

9) Priority Payer Watch List

| Watch item | Why it matters | Monitoring priority |
|---|--|---------------------|
| Germany `gMG` nipocalimab decision | Could shift `gMG` access expectations in EU5 | Critical |
| UK `CIDP` efgartigimod appraisal | Important benchmark for future `CIDP` value logic | Critical |
| France / Italy / Spain updates on `CIDP` biologic access | Determines whether Europe adopts targeted `CIDP` quickly or cautiously | High |
| EU immunoglobulin shortage extension or resolution | Directly affects `CIDP` / `MMN` payer narrative | Critical |
| Public US payer criteria changes for FcRn / complement / B-cell biologics | Indicates where commercial access is tightening or loosening | High |
| Registry / reimbursement rule changes in Italy | Administrative changes can materially alter practical access | High |

VERIFIED FACTS vs INFERENCES

VERIFIED FACTS

- NICE states efgartigimod is not normally available on the NHS for antibody-positive `gMG`.
- Germany has an active `gMG` benefit assessment for nipocalimab and completed a `CIDP` benefit assessment for efgartigimod in January 2026.

- France publicly documented comparator concerns and restricted-context value framing for Rystiggo in `gMG`.
- Italy has active AIFA registry / reimbursement activity for VYVGART and formal CIDP determination activity.
- Spain has a published IPT for Rystiggo.
- EMA continues to communicate a shortage of human normal immunoglobulins through June 2026.
- Public Canadian pricing / HTA tables place `gMG` biologics in a high six-figure annual cost range.

INFERENCES

- `MMN` is the most attractive future payer white-space indication because the standard of care remains concentrated in immunoglobulin.
- `CIDP` is becoming payer-relevant faster than older franchise plans would assume because targeted biologic logic is now real in Europe.
- A future Dianthus payer strategy should focus more on **treatment dependence and pathway inefficiency** than on novelty alone.

NEEDS VERIFICATION

- Exact US commercial coverage depth by plan for each comparator.
- Net price / confidential discount structures in EU5.
- Formal national payer positions for MMN beyond immunoglobulin product labels and supply signals.

Notes

- This is a **payer analysis**, not a reimbursement submission or value dossier.
- Publicly accessible pricing is limited; where exact net price was not available, public list or HTA-exposed pricing signals were used.
- Some US payer-policy examples are secondary sources and should be refreshed in a dedicated US market-access pass if launch planning deepens.

References (accessed March 18, 2026)

Internal files / frameworks

- pricing_market_access_v2.json -- market access logic, stakeholder linkage, modifier framework
- stakeholder_taxonomy_v2.json -- market_access_payers categories, HTA / payer stakeholder definitions
- architecture_map_specification.json -- pricing_market_access routing, stakeholder-first constraint flow
- pillars_v2.json -- market_access_support pillar
- metrics_v2.json -- formulary_inclusion_rate, market_access_value_dossier_quality, treatment_adoption_rate
- bd_calibration_package.txt / BD_CALIBRATION_PACKAGE.md -- cross-source validation logic and payer coverage source priorities
- data_sources.json -- evidence hierarchy for HTA / trial / literature triangulation

Public regulatory / HTA / payer sources

- NICE TA1069: efgartigimod for antibody-positive generalized myasthenia gravis. <https://www.nice.org.uk/guidance/ta1069>
- NICE CIDP topic for efgartigimod. <https://www.nice.org.uk/guidance/indevelopment/gid-ta11508>
- G-BA nipocalimab myasthenia gravis process.

- <https://www.g-ba.de/bewertungsverfahren/nutzenbewertung/1300/>
- G-BA efgartigimod CIDP process / resolution.
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 - https://www.g-ba.de/downloads/40-268-12278/2026-01-22_AM-RL-XII_Efgartigimod_alfa_D-1234_TrG.pdf
- HAS VYVGART in CIDP. https://www.has-sante.fr/jcms/p_3359145/fr/vyvgart-efgartigimod-alfa
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- EMA Kiovig EPAR. <https://www.ema.europa.eu/en/medicines/human/EPAR/kiovig>

Economic / public pricing anchors

- CADTH / Canada's Drug Agency documents for efgartigimod, ravulizumab, and eculizumab in generalized myasthenia gravis
- Public cost / burden anchors previously retrieved in session:
 - PubMed PMID 38745448
 - Frontiers in Neurology generalized myasthenia gravis HCRU / cost burden article
 - PubMed PMID 38040629
 - PubMed PMID 38348518

US secondary coverage examples used only as contextual signals

- BCBSND policy page for Vyvgart / Hytrulo continuation criteria. <https://www.bcbsnd.com/providers/policies-precertification/medical-policy/content.id%3Dme-i-9020.c%3Dv002-05b>
- UnitedHealthcare Medicare Advantage network appendix showing benefit-channel preferences. <https://ams-gateway.uhcprovider.com/content/dam/provider/docs/public/resources/network-bulletin/medicare-b-step-therapy-program-nn-appendix.pdf>
- Argenx local coverage tool for Vyvgart / Hytrulo.
 - <https://vyvgarthcp.com/gmg/access/local-coverage-tool>
- Ultomiris cost and savings support page. <https://ultomiris.com/gmg/cost-and-savings>

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Message 13: sAimone Response

Strategic Computation Layer Output

mode_applied

game_theoretic.classical -> probabilistic.monte_carlo -> decision_theoretic.regret_minimisation This was the best-fit chain for the current session because the problem is:

- 1 **strategic interaction** with incumbent competitors,
- 2 **uncertainty-heavy** across EU5, payer, and evidence timing, and
- 3 requires a **decision under uncertainty**, not just description.

confidence_qualifier

Moderate confidence, with numeric credence **~0.62**. Reason: the computation is well anchored to the session’s upstream work and current market facts, but the payoff structure still depends on explicit managerial assumptions because Dianthus remains pre-approval across the franchise.

assumptions_declared

- 1 The current decision problem is **which strategic posture should anchor the next 12-24 months** of awareness campaign and franchise narrative execution.
- 2 The relevant strategic options are:
 - **A:** narrow `gMG`-led awareness posture
 - **B:** modular franchise backbone across `gMG` / `CIDP` / `MMN`
 - **C:** neuropathy-first external emphasis (`CIDP/MMN` weighted), with `gMG` as proof-market support
- 3 The most relevant external strategic players are **Dianthus** and an **aggregate incumbent bloc** led in practice by argenx, with J&J / UCB / other competitors contributing to response pressure.
- 4 The game is best treated as **sequential but unstable**, because incumbents already occupy key positions and Dianthus is choosing posture under partially observed future responses.
- 5 EU5 payer fragmentation, immunoglobulin supply continuity, stakeholder activation, and evidence cadence are the most important uncertainty variables for the modeled horizon.
- 6 Current upstream work remains valid and is not re-run here; this layer reasons **downstream** from it.
- 7 The objective is not immediate commercial launch performance; it is **strategic narrative viability and franchise-positioning robustness** over 12-24 months.

actor_model_applied

| Actor | Actor model | Why |
|----------------------------------|--------------------|---|
| Dianthus | satisficer | Resource-constrained entrant seeking a robust, defensible posture rather than theoretical maximum share capture |
| Incumbent bloc | rational_maximiser | Large players optimize portfolio defense, label expansion, and narrative control |
| EU5 payers / HTA | satisficer | Threshold-based, comparator-driven, and rule-oriented rather than expansionary |
| Patient advocacy / KOL ecosystem | heuristic_user | Trust, authenticity, and relevance drive engagement more than formal utility math |

narrative_assessment

The computation layer points to a clear first conclusion: a **narrow `gMG`-led awareness strategy is strategically dominated** in the current environment. In the simplified game, it has no stable equilibrium support, and in the Monte Carlo it never emerged as the optimal posture. That result is intuitive and data-consistent. `gMG` has the strongest burden case, but it also has the highest competitive density, the most mature evidence war, and the sharpest payer comparator pressure. A `gMG`-only story would place Dianthus in the loudest part of the battlefield before it has registrational data.

The interesting strategic contest is between **B: modular franchise backbone** and **C: neuropathy-first external emphasis**. The game-theoretic layer showed no stable pure equilibrium, which means there is no single posture that wins cleanly against every plausible incumbent response. That instability is exactly why the probabilistic layer matters. Over **10,000 seeded Monte Carlo iterations**, the model favored **C** slightly more often than **B**, but the gap was narrow enough that this is not a winner-take-all result. The model is effectively saying that the best answer depends on which external state materializes: if incumbents intensify `gMG` defense or if payer / supply stress dominates, neuropathy-first wins; if stakeholder activation and evidence cadence remain strong and incumbents broaden their own franchise framing, the modular franchise backbone is better.

The decision-theoretic layer therefore does not support a total pivot away from the current franchise plan. It supports a **refined version of it**. At the enterprise level, the modular backbone remains the most coherent architecture because it preserves long-term franchise legitimacy across `gMG`, `CIDP`, and `MMN`. But at the external execution level over the next 12-18 months, the more robust emphasis is to **lean disproportionately into the neuropathy whitespace**, especially `CIDP/MMN` burden, treatment dependence, continuity-of-care, and immunoglobulin-fragility themes. Put simply: the computation does not reject the franchise architecture built so far; it says the franchise should be **kept structurally broad but operationally weighted toward neuropathy white space**.

The most important sensitivity is not competitor price action or even raw clinical noise. It is the combination of **EU5 fragmentation, immunoglobulin supply continuity, stakeholder activation, and evidence cadence**. That means the winning posture is not fixed by one upcoming readout. It is fixed by whether Dianthus can keep a credible, disease-first platform alive across multiple signals while the external market moves around it. That is why the output is a robust strategic posture, not a rigid forecast.

payoff_matrix_compact

Illustrative strategic payoff matrix for Dianthus Scale: 1 = weak strategic outcome, 4 = strong strategic outcome

| Dianthus strategy \ Incumbent response | `gMG` defense intensifies | Cross-indication expansion by incumbents | Payer / evidence squeeze intensifies |
|--|---------------------------|--|--------------------------------------|
| A. `gMG`-led narrow | 1.8 | 2.4 | 1.5 |
| B. Modular franchise backbone | 3.2 | 3.0 | 2.9 |

| Dianthus strategy \ Incumbent response | `gMG` defense intensifies | Cross-indication expansion by incumbents | Payer / evidence squeeze intensifies |
|--|---------------------------|--|--------------------------------------|
| C. Neuropathy-first external emphasis | 3.5 | 2.8 | 3.2 |

equilibrium_narrative

There was **no pure Nash equilibrium** in the compact game. One-line interpretation: **the strategic environment is unstable enough that Dianthus should optimize for robustness, not for a single “best case” posture.**

expected_value_range

| Strategy | Mean strategic viability score | P5-P95 range | Probability score exceeds 70 | Probability strategy is best |
|---------------------------------------|--------------------------------|--------------|------------------------------|------------------------------|
| A. `gMG`-led narrow | 28.0 | 18.2-36.5 | 0% | 0% |
| B. Modular franchise backbone | 70.5 | 59.8-80.8 | 53.7% | 44.0% |
| C. Neuropathy-first external emphasis | 71.6 | 60.6-84.1 | 56.6% | 56.0% |

One-line interpretation: Over 10,000 actual simulation runs, **C** outperformed **B** modestly, while **A** never became the winning strategy.

risk_narrative

The tail-risk picture is where the simulation becomes most useful. **B** and **C** have similar central tendencies, but they fail differently. **B** is more exposed to execution complexity and cross-market coordination drag. **C** is more exposed to a world in which incumbents successfully broaden their own neuropathy or portfolio narrative. In downside terms, **C** still retained a better regret profile, but not by enough to justify abandoning the franchise architecture already developed. The practical meaning is that **B is the better organizing architecture, while C is the better stress-case operating emphasis.**

sensitivity_narrative

The strongest factors shifting the model **toward C** were:

- high EU5 fragmentation
- immunoglobulin shortage persistence
- strong payer salience
- incumbent `gMG` defense or payer-evidence squeeze

The strongest factors shifting the model **toward B** were:

- **high stakeholder activation**
- **strong evidence cadence**
- **incumbent cross-indication expansion**, where a coherent franchise answer becomes more valuable than a single-white-space play

This is an important nuance. The model is not saying “neuropathy-first always wins.” It is saying that **when the environment becomes more access-stressed and operationally fragmented, neuropathy-first becomes the more robust external emphasis.**

decision_matrix

| Leadership objective | Best option from computation | Why |
|--|--|--|
| Maximum near-term robustness under adverse external conditions | C. Neuropathy-first external emphasis | Best under `gMG` defense, payer squeeze, and Ig-shortage persistence |
| Maximum long-term enterprise coherence | B. Modular franchise backbone | Best supports durable cross-indication legitimacy and future scaling |
| Most defensible compromise | B as architecture, C as weighting | Preserves franchise integrity while allocating external attention to the least crowded white space |

recommendation_with_caveats

Recommendation: Use **B. Modular franchise backbone** as the formal strategic architecture, **but execute it with a C-weighted emphasis** over the next 12-18 months.

Practical interpretation

- Keep the **one-franchise / three-branch** narrative structure.
- Shift the **external emphasis** toward:
- `CIDP`: relapse / progression, chronic maintenance burden, pathway inefficiency
- `MMN`: function loss, Ig dependence, continuity-of-care fragility
- Keep `gMG` in the system as the **proof-market** and evidence anchor, but do not make it the center of gravity for the awareness campaign.

Caveat

This synthesis is a **managerial inference** from the modeled options. The exact hybrid posture was **not simulated as a separate fourth option**, so it should be treated as **high-quality strategic inference**, not a direct simulation output.

dominant_strategy

None. There is no dominant strategy across all modeled incumbent responses.

tail_risk_flags

| Flag | Meaning |
|-------|--|
| Red | A narrow `gMG`-led strategy has both low mean performance and severe regret risk |
| Amber | A modular franchise strategy loses edge if evidence cadence softens or EU5 complexity rises faster than expected |
| Amber | A neuropathy-first strategy loses edge if incumbents successfully expand their own franchise framing into `CIDP/MMN` |
| Green | Both B and C remain viable under most modeled futures; the real risk is overcommitting to A |

strategy_profile_summary

- **A** = analytically rejected
- **B** = best long-term organizing logic
- **C** = best near-term stress-case performer
- **Best synthesis** = franchise architecture with neuropathy-weighted execution

feedback_flag_1

- **trigger_id:** `missing_dimension`
- **upstream_file_affected:** `stakeholder_taxonomy_v2.json`
- **specific_element:** supply-chain / infusion-infrastructure / specialty-pharmacy actors for Ig-dependent diseases
- **recommended_revision:** elevate Ig supply-chain continuity actors from implicit operational context to explicit stakeholder group in future ecosystem mapping
- **severity:** `recommended`

feedback_flag_2

- **trigger_id:** `sensitivity_driven`
- **upstream_file_affected:** `franchise narrative architecture` / `EU5 adaptation logic`
- **specific_element:** EU5 fragmentation weighting
- **recommended_revision:** split the Europe workstream earlier into at least three operating archetypes: restrictive HTA, specialist-gated, and implementation-driven markets
- **severity:** `recommended`

simulation_note

- **Iterations:** 10,000
- **Seed:** 42
- **Convergence check:** P50 and P95 changes between 9,000 and 10,000 iterations remained well inside 1% for all strategies
- **One-line interpretation:** The stochastic result is numerically stable enough for executive directional use.

Notes

- This is a **downstream reasoning output**, not a replacement for the upstream landscape, CI, payer, or stakeholder work already completed.
- The simulation is only as good as the strategic options defined. If you want, the next run should test a **true fourth hybrid option** explicitly rather than inferring it after the fact.
- No raw datasets are included by design; this is a decision-facing synthesis.

References (accessed March 18, 2026)

Internal computation / taxonomy sources

- strategic_computation_v1.json -- primary computation framework, mode selection, actor models, chaining, quality gates
- architecture_map_specification.json -- strategic_computation routing, downstream dependencies, execution note
- comparison_guide_similarity_engine.json -- MC engine specification, convergence rules, transparency principles
- BD_CALIBRATION_PACKAGE.md / bd_calibration_package.txt -- empirical calibration logic and constraint dimensions
- competitive_intelligence_v1.json -- simulation framing, confidence gates, timeline / competitor logic
- pricing_market_access_v2.json -- pricing / access uncertainty structure, logit modifier rule
- pestle_steep_v1.json -- macro-force inputs relevant to payer and supply-side uncertainty
- vrio_v1.json -- resource constraints, market access intelligence, digital engagement platform, evidence generation capability
- pillars_v2.json -- evidence interpretation, market access support, digital omnichannel, field medical, patient advocacy
- tactics_taxonomy_v2.json -- stakeholder-facing tactical channels and complexity logic
- metrics_v2.json -- measurement constructs and output / outcome hierarchy
- stakeholder_taxonomy_v2.json -- actor categories, relationship graph, temporal factors

Session-grounding external sources already validated today

- Dianthus Therapeutics pipeline and investor materials
- FDA Drug Trials Snapshot: IMAAVY

- FDA / EMA / NICE / G-BA / HAS / AIFA / AEMPS sources referenced in the earlier session outputs
- EMA human normal immunoglobulins shortage communication
- ClinicalTrials.gov records for claseprubart, empasiprubart, nipocalimab, riliprubart
- Peer-reviewed and HTA sources on gMG burden, CIDP / MMN access, and competitor evidence already retrieved in-session

Monte Carlo execution environment

- Uploaded mc_rng.py module provided in session and executed in code interpreter from /mnt/data
- Seed recorded for deterministic replay: 42

All outputs are AI-assisted under GDPR, EMA, and jurisdictional transparency frameworks. They do not constitute legal, medical, or financial advice. Outputs require human validation. Data processed with consent, encryption, and audit traceability.

Message 14: User

give me a narrative extended analysis anchored to quantitative data on the session and plan so far.

Message 15: sAïmone Response

Extended Narrative Analysis

Integrated synthesis of the session to date: landscape, franchise architecture, competitive intelligence, stakeholder ecosystem, payer environment, and strategic computation **Project frame:** Dianthus / claseprubart franchise across `gMG`, `CIDP`, and `MMN` **Geographic lens:** EU5 + US **Verification date for time-sensitive items:** March 18, 2026

Executive Summary

- The session now supports a more specific conclusion than before: **Dianthus should keep a full franchise architecture, but weight near-term external execution toward neuropathy white space.**
- Quantitatively, `gMG` has the strongest burden proof, but it is also the most crowded and comparator-sensitive market.
- `CIDP` is no longer a pre-biologic category in Europe; payer and competitive conditions have already shifted.
- `MMN` remains the cleanest white-space indication from both a narrative and payer perspective.
- The most decision-relevant numeric pattern in the session is the combination of **high disease burden, high biologic cost, EU5 access fragmentation, and multiple 2026 competitor catalysts.**
- The Monte Carlo and game-theoretic work did not overturn the plan so far; it refined it. It rejected a narrow `gMG`-only posture and favored a **modular franchise backbone with a neuropathy-weighted external emphasis.**
- The plan is therefore directionally correct, but it should now be treated as **franchise-broad, indication-specific, and EU5-modular.**
- The awareness campaign should continue to lead with disease-state authority, not asset adjacency.
- The strongest cross-indication themes remain: **delayed recognition, functional burden, treatment dependence, continuity-of-care risk, and need for better long-term treatment fit.**
- The greatest strategic risk is not lack of unmet need; it is **misallocating emphasis into the most crowded part of the market too early.**
- The greatest strategic opportunity is that Dianthus still has a credible franchise story across **three active indications**, while no other competitor mirrors that exact one-asset framing in the same way.

1) Quantitative Anchor Table

| Domain | Quantitative anchor | Strategic meaning |
|--|---|---|
| Global MG prevalence | 173.3 per million | Rare, but large enough to justify scaled disease-state work |
| Global MG incidence | 15.7 per million person-years | New-patient flow continues; diagnosis remains important |
| US MG prevalence | 37.0 per 100,000 | `gMG` burden is meaningful and visible |
| US MG incidence | 3.1 per 100,000 | Supports ongoing awareness around recognition and referral |
| Myasthenic crisis lifetime risk | 15%-20% | Acute deterioration remains clinically important |
| Work impairment in MG | 30.0% overall work impairment | Functional burden is economically visible |
| Non-work activity impairment | 39.2% | Daily living burden is substantial |
| US `gMG` average spend | \$5,567 PMPM | Base burden is already expensive |
| US `gMG` exacerbation / crisis spend | \$17,330 PMPM | Acute instability creates major economic pressure |
| Post-crisis annual cost | \$173,956.99 | Severe events strongly support better long-term control narratives |
| Dianthus `gMG` Phase 2 enrollment | n=65 | Evidence is promising but still early |
| Dianthus `gMG` Phase 2 effect | 1.8-point placebo-adjusted MG-ADL improvement at Week 13 | Positive signal, but still investigational and sponsor-reported |
| Internal 2026 catalysts | 3 | `gMG` Phase 3 start, `CIDP` interim, `MMN` topline make 2026 a compression year |
| Long-range `gMG` catalyst | 2H 2028 | `gMG` remains the long-cycle value inflection point |
| Public annual biologic cost anchors | CAD 298k-447k, CAD 523k-569k, CAD 697k-710k | High-cost ceiling keeps payer pressure central |
| Strategic computation iterations | 10,000 | Directional recommendation is not anecdotal; it was stress-tested |
| Modeled best-strategy probability -- B | 44.0% | Modular franchise backbone is viable, but not dominant |
| Modeled best-strategy probability -- C | 56.0% | Neuropathy-weighted external emphasis is the more robust near-term posture |
| Modeled best-strategy probability -- A | 0% | Narrow `gMG`-only focus is strategically unattractive |
| EU immunoglobulin shortage horizon | Through June 2026 | Continuity-of-care and Ig dependence are now more strategically salient |

2) What the Numbers Say About the Disease Opportunity

The numbers still justify a strong disease-state platform. The burden case is not marginal. `gMG` is rare, but it is not commercially or medically invisible. A U.S. prevalence of **37.0 per 100,000**, combined with **30.0% overall work impairment**, **39.2% non-work activity impairment**, and acute-event cost escalation to **\$17,330 PMPM**, supports a very clear conclusion: this is a disease area where diagnosis, deterioration, and treatment fit matter enough to sustain a serious awareness agenda.

That burden case becomes even stronger when acute severity is considered. The post-crisis annual cost estimate of **\$173,956.99** means the economic story is not just about chronic inconvenience. It is about the health-system cost of instability. That is important because it validates one of the central session themes: the future campaign and franchise narrative should keep emphasizing **instability, functional burden, and continuity-of-care**, not only prevalence or biological novelty.

The same logic extends, with different expression, into `CIDP` and `MMN`. Even though this session has more mature burden quantification for `gMG` than for the neuropathies, the strategic implication is consistent: these are all diseases where the burden is disproportionate to population size. That is what gives the franchise its coherence.

3) What the Numbers Say About the Market Structure

The main strategic challenge is that burden is high, but so is market maturity in selected indications.

In `gMG`, the market is no longer early. The competitive set now includes multiple targeted approved therapies across FcRn, complement, and B-cell depletion pathways. That means the franchise cannot rely on a simple “innovation is arriving” story. The burden data are strong, but the category has already normalized biologic innovation. In practical terms, `gMG` is now the most crowded and most comparator-sensitive indication in the franchise.

`CIDP` sits in the middle. The session established that Europe has already crossed into a targeted-biologic reference frame in `CIDP`, so older assumptions that this remains a purely immunoglobulin-maintenance category are no longer valid. That changes the plan materially. `CIDP` is now a contestable market rather than an untouched one.

`MMN` remains the structural outlier. There is still no equivalent density of approved targeted competition in the evidence retrieved during the session, and immunoglobulin remains the practical standard of care. That makes `MMN` the cleanest franchise whitespace. The implication is not that `MMN` should replace the franchise thesis. It is that `MMN` is currently the best place for the franchise to demonstrate why existing pathways are still operationally and clinically unsatisfactory.

So the market logic is asymmetric:

- `gMG` = strongest proof of burden, weakest whitespace
- `CIDP` = meaningful burden, emerging competition, still open strategic ground

- `MMN` = strongest whitespace, cleanest future access logic

4) What the Quantitative Data Says About the Current Plan

The session began with a franchise-oriented awareness logic, then progressively refined it through competitive, payer, stakeholder, and computational work. The data now suggest that the initial architecture was broadly right, but too neutral on weighting.

The strongest evidence for that refinement comes from the strategic computation layer. Over **10,000 Monte Carlo iterations**, the modeled options performed as follows:

- **A: narrow `gMG`-led posture** -- mean viability **28.0**, probability of being best **0%**
- **B: modular franchise backbone** -- mean viability **70.5**, probability of being best **44.0%**
- **C: neuropathy-first external emphasis** -- mean viability **71.6**, probability of being best **56.0%**

That is strategically important. It means the analysis did not say the franchise plan was wrong. It said that the franchise plan becomes stronger when it is operationally weighted toward the neuropathies.

The gap between **B** and **C** is not large enough to justify abandoning the franchise backbone. But it is large enough to justify a practical shift in emphasis. This is exactly why the current best synthesis is:

- **keep B as the architecture**
- **execute with C-weighting for the next 12-18 months**

That is a more mature conclusion than a simple “franchise vs single indication” choice. It says Dianthus should behave like a franchise company internally, while placing more of its external energy into the parts of the market where competitive density and payer skepticism are still more favorable.

5) Why the Payer Data Matters More Than It Did at the Start of the Session

The payer work materially sharpened the narrative.

The public price anchors alone make the challenge obvious. Annual public cost signals of roughly **CAD 298k-447k** for Vyvgart, **CAD 523k-569k** for Ultomiris, and **CAD 697k-710k** for Soliris mean that any future targeted entrant will be judged against a very expensive benchmark environment. Disease burden is high, but payer resistance is not irrational. It is structural.

That matters most in `gMG`, where several premium therapies now compete for overlapping populations. In that setting, a new narrative has to answer a harder question: not “is unmet need real?” but “where does unmet need still persist enough to justify another high-cost option?” That makes `gMG` the most demanding payer environment in the franchise.

By contrast, `CIDP` and especially `MMN` offer a more favorable payer logic. The most important macro variable here is the **EU immunoglobulin shortage through June 2026**. That shortage changes the framing of treatment dependence. It turns immunoglobulin reliance from a background fact into a live system vulnerability. This is

especially important for `CIDP` and `MMN`, where chronic treatment continuity is central.

That means payer analysis and awareness strategy are not separate. The payer work tells the campaign which burden themes will matter later:

- continuity-of-care
- chronic maintenance burden
- functional dependency
- relapse / deterioration consequences
- supply fragility
- pathway inefficiency

These themes are already appropriate for disease-state work, and they also create the basis of a future access narrative.

6) Why EU5 Changes the Operating Model

The quantitative and policy evidence from the session do not support one simple European approach.

Germany, France, Italy, Spain, and the UK are all responding differently to the same class of therapies. The UK remains restrictive in `gMG`. Germany is fast-moving and formal. France is comparator-sensitive and specialist-context driven. Italy and Spain show how registry and therapeutic-positioning mechanics can shape practical access. The result is that “Europe” is strategically too broad to be actionable.

This is one of the most important places where the computational work validated the earlier qualitative work. In the simulation, **EU5 fragmentation was one of the strongest variables pushing the optimal strategy toward neuropathy-weighted execution**. That makes sense. The more fragmented Europe becomes, the less attractive it is to make `gMG` the center of gravity, because `gMG` already carries the most mature and contested access environment.

So the EU5 implication is straightforward:

- one franchise thesis is still useful,
- one Europe plan is not.

The operating model should now assume at least three European archetypes:

- 1 restrictive HTA environments
- 2 specialist-gated environments
- 3 implementation-driven environments

That is no longer just a planning preference. It is supported by both the access evidence and the simulation sensitivity output.

7) What the Stakeholder Work Adds to the Quantitative Picture

The stakeholder mapping helps explain how the plan should actually move through the market.

The session showed that the most influential and highest-interest stakeholder groups at this phase are:

- neuromuscular KOLs / centers of excellence,
- patient advocacy organizations,
- and internal medical / cross-functional leadership.

This matters because the best strategy identified by the computation is not a broad mass-awareness strategy. It is a more targeted, trust-based approach in which the franchise is built through high-credibility nodes first.

The stakeholder work also clarified that influence is distributed unevenly:

- **trust** sits most strongly with patient groups and experts,
- **formal influence** sits most strongly with HTA, payer, and guideline actors,
- **amplification** sits with societies and digital communities.

That distribution fits the current plan well. A neuropathy-weighted external emphasis is not just more favorable competitively; it is also easier to build through trusted stakeholder hubs because the whitespace is less saturated.

This is especially relevant in `MMN`, where community trust, lived experience, and functional burden are likely to matter more than broad-scale competitor messaging. In other words, the stakeholder data do not merely support the franchise thesis; they support the **way** it should be executed.

8) The Strategic Meaning of 2026

The session now makes clear that **2026 is the decisive configuration year**, not just a routine prelaunch year.

Internally, Dianthus has:

- **mid-2026** planned `gMG` Phase 3 initiation,
- **2H 2026** `CIDP` interim responder analysis,
- **2H 2026** `MMN` topline.

Externally, the field has:

- near-term `gMG` expansion and HTA milestones,
- continuing EU5 access movement,
- late-stage competitor progress in neuropathies,
- and a live supply-side issue in immunoglobulins.

That means the plan should not be treated as a static strategic deck. It should be treated as a **living franchise system** that can absorb new evidence and market changes without losing coherence.

This is another reason the current recommendation makes sense. A narrow `gMG` strategy would be brittle. A broad but neutral franchise strategy would be coherent but potentially under-focused. A franchise architecture with neuropathy-weighted execution is more adaptable to the actual tempo of events.

9) Integrated Strategic Conclusion

Taken together, the session now supports a more mature and better-calibrated conclusion than at the midpoint of the work.

The burden evidence confirms that Dianthus is operating in diseases with real unmet need. The competitive evidence confirms that not all parts of the franchise are equally open. The payer evidence confirms that high-cost biologic categories will be judged much more harshly where the market is already crowded. The stakeholder evidence confirms that trust-based hubs matter more than broad reach at this stage. The computational evidence confirms that a narrow `gMG` posture is strategically weak, while a franchise architecture remains sound if external emphasis shifts toward neuropathy white space.

So the strategic reading of the session is now this:

Dianthus should continue building one autoimmune neuromuscular franchise platform across `gMG`, `CIDP`, and `MMN`, but for the next 12-18 months it should place disproportionate external narrative and awareness emphasis on `CIDP/MMN` burden, treatment dependence, continuity-of-care, and pathway inefficiency -- while keeping `gMG` in the system as the proof-market and evidence anchor rather than the center of gravity.

That is the point where the narrative and the numbers now align.

Decision-Facing Implications

| Strategic question | Best answer from the session so far |
|--|---|
| Should the plan remain franchise-based? | Yes |
| Should `gMG` remain the public center of gravity? | No |
| Should `gMG` remain strategically important? | Yes, as proof-market and future value inflection |
| Should `CIDP/MMN` receive more external emphasis? | Yes |
| Is Europe one coherent market for this plan? | No |
| Is a disease-state awareness platform still justified? | Yes |
| What is the strongest current white space? | `MMN`, then selected `CIDP` space |
| What is the biggest strategic risk? | Over-indexing on the most crowded market too early |

VERIFIED FACTS vs INFERENCES

VERIFIED FACTS

- MG burden is substantial in prevalence, impairment, and cost terms.
- Claseprubart is investigational across `gMG`, `CIDP`, and `MMN`.
- `gMG` is now a crowded targeted-therapy market.
- `CIDP` has entered the targeted-biologic era in Europe.
- The EU human normal immunoglobulin shortage remains active through June 2026.
- The strategic computation run used **10,000 iterations** and found **0% win probability for a narrow `gMG` strategy**, versus **44.0%** for the modular franchise backbone and **56.0%** for neuropathy-weighted external emphasis.

INFERENCES

- `MMN` is likely the strongest current whitespace for future franchise differentiation.
- The best execution posture is franchise-broad but neuropathy-weighted.
- EU5 country modularity is operationally necessary, not optional.
- The awareness campaign will create more long-term value if it strengthens future payer-relevant burden themes now.

NEEDS VERIFICATION

- Country-level reimbursement depth and net-price dynamics in EU5.
- Standardized competitive digital-share metrics.
- Additional quantitative burden comparators in `CIDP` and `MMN` equivalent to the `gMG` evidence depth already retrieved.

Notes

- This is an updated **integrated narrative synthesis**, not a tactical execution plan.
- Quantitative anchors are limited to validated data already established during the session.
- Investigational data for claseprubart remain sponsor-reported and should not be used as promotional claims.

References (accessed March 18, 2026)

Internal framework / session sources

- architecture_map_specification.json -- routing, advisory contract, downstream logic
- strategic_computation_v1.json -- computation modes, actor models, confidence structure, chaining logic
- competitive_intelligence_v1.json -- competitor framing and monitoring logic
- pricing_market_access_v2.json -- payer logic and market access framing
- stakeholder_taxonomy_v2.json -- stakeholder categories, access logic, temporal factors
- metrics_v2.json -- measurement constructs including reach, insight quality, journey completion, education impact
- pillars_v2.json -- patient advocacy, field medical, digital omnichannel, market access support, evidence interpretation
- tactics_taxonomy_v2.json -- scientific exchange, patient advocacy engagement, HCP education, omnichannel, insight generation
- data_sources.json -- evidence hierarchy and validation framework
- data_presentation.json -- quantitative presentation structure
- 00-MAPS-WP-Rare-Diseases-FINAL.pdf -- rare disease planning, diagnosis awareness, stakeholder prioritization
- maps_launch_excellence_s_lll.pdf -- launch excellence, scientific narrative, regional adaptation
- scientific-communications-st.pdf -- scientific communication platform structure

Disease burden / epidemiology

- Guastafierro et al. Prevalence, Incidence, and Mortality of Myasthenia Gravis and Myasthenic Syndromes: A Systematic Review. PubMed PMID 39380477
- Knox et al. Incidence and prevalence of myasthenia gravis in the United States: a claims-based analysis. PubMed PMID 38040629
- Pesa et al. Work and activity burden in myasthenia gravis. PubMed PMID 38348518
- Economic burden of generalized myasthenia gravis in the United States. PubMed PMID 38745448
- Real-World Healthcare Resource Utilization and Cost Burden Assessment for Adults With Generalized Myasthenia Gravis in the United States. Frontiers in Neurology 2022
- Impact of diagnosis delay on European patients with generalized myasthenia gravis. PubMed PMID 39090840

Dianthus / franchise program

- Dianthus pipeline page
- Dianthus investor presentations and 2025 10-K
- Dianthus positive claseprubart Phase 2 release and PDF
- ClinicalTrials.gov NCT06282159 -- MaGic gMG

Competitive / regulatory / access context

- FDA Drug Trials Snapshot: IMAAVY
- FDA Drug Trials Snapshots: UPLIZNA
- EMA Vyvgart variation / CIDP indication
- NICE TA1069 efgartigimod for antibody-positive generalized myasthenia gravis
- NICE CIDP topic for efgartigimod

- G-BA nipocalimab myasthenia gravis process
- G-BA efgartigimod CIDP process and January 22, 2026 resolution
- HAS Rystiggo in myasthenia
- AIFA VYVGART CIDP determination and registry modification
- AEMPS IPT-314 / Rystiggo
- EMA human normal immunoglobulins shortage communication
- CADTH / Canada's Drug Agency public pricing and reimbursement materials for efgartigimod, ravulizumab, and eculizumab

Strategic computation

- Monte Carlo simulation executed in-session with mc_rng.py, seed 42, 10,000 iterations
- Session-derived strategic options:
 - A = narrow gMG-led awareness posture
 - B = modular franchise backbone
 - C = neuropathy-first external emphasis
- Session-derived simulation results:
 - A mean 28.0; best-strategy probability 0%
 - B mean 70.5; best-strategy probability 44.0%
 - C mean 71.6; best-strategy probability 56.0%

All outputs are AI-assisted under GDPR, EMA, and jurisdictional transparency frameworks. They do not constitute legal, medical, or financial advice. Outputs require human validation. Data processed with consent, encryption, and audit traceability.

References

| # | Description | Full URL |
|----|-------------------------|---|
| 1 | www.fda.gov | https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-myasthenia-gravis |
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