

Driving Long-Term Growth: Rocatinlimab and UPLIZNA® Update

September 24, 2024

AMGEN



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Our results may be affected by our ability to successfully market both new and existing products domestically and internationally, clinical and regulatory developments involving current and future products, sales growth of recently launched products, competition from other products including biosimilars, difficulties or delays in manufacturing our products and global economic conditions. In addition, sales of our products are affected by pricing pressure, political and public scrutiny and reimbursement policies imposed by third-party payers, including governments, private insurance plans and managed care providers and may be affected by regulatory, clinical and guideline developments and domestic and international trends toward managed care and healthcare cost containment. Furthermore, our research, testing, pricing, marketing and other operations are subject to extensive regulation by domestic and foreign government regulatory authorities. Our business may be impacted by government investigations, litigation and product liability claims. In addition, our business may be impacted by the adoption of new tax legislation or exposure to additional tax liabilities. If we fail to meet the compliance obligations in the corporate integrity agreement between us and the U.S. government, we could become subject to significant sanctions. Further, while we routinely obtain patents for our products and technology, the protection offered by our patents and patent applications may be challenged, invalidated or circumvented by our competitors, or we may fail to prevail in present and future intellectual property litigation. We perform a substantial amount of our commercial manufacturing activities at a few key facilities, including in Puerto Rico, and also depend on third parties for a portion of our manufacturing activities, and limits on supply may constrain sales of certain of our current products and product candidate development. An outbreak of disease or similar public health threat, such as COVID-19, and the public and governmental effort to mitigate against the spread of such disease, could have a significant adverse effect on the supply of materials for our manufacturing activities, the distribution of our products, the commercialization of our product candidates, and our clinical trial operations, and any such events may have a material adverse effect on our product development, product sales, business and results of operations. We rely on collaborations with third parties for the development of some of our product candidates and for the commercialization and sales of some of our commercial products. In addition, we compete with other companies with respect to many of our marketed products as well as for the discovery and development of new products. Further, some raw materials, medical devices and component parts for our products are supplied by sole third-party suppliers. Certain of our distributors, customers and payers have substantial purchasing leverage in their dealings with us. The discovery of significant problems with a product similar to one of our products that implicate an entire class of products could have a material adverse effect on sales of the affected products and on our business and results of operations. Our efforts to collaborate with or acquire other companies, products or technology, and to integrate the operations of companies or to support the products or technology we have acquired, may not be successful. There can be no guarantee that we will be able to realize any of the strategic benefits, synergies or opportunities arising from the Horizon acquisition, and such benefits, synergies or opportunities may take longer to realize than expected. We may not be able to successfully integrate Horizon, and such integration may take longer, be more difficult or cost more than expected. A breakdown, cyberattack or information security breach of our information technology systems could compromise the confidentiality, integrity and availability of our systems and our data. Our stock price is volatile and may be affected by a number of events. Our business and operations may be negatively affected by the failure, or perceived failure, of achieving our environmental, social and governance objectives. The effects of global climate change and related natural disasters could negatively affect our business and operations. Global economic conditions may magnify certain risks that affect our business. Our business performance could affect or limit the ability of our Board of Directors to declare a dividend or our ability to pay a dividend or repurchase our common stock. We may not be able to access the capital and credit markets on terms that are favorable to us, or at all.

Any scientific information discussed in this presentation relating to new indications for our products is preliminary and investigative and is not part of the labeling approved by the U.S. Food and Drug Administration for the products. The products are not approved for the investigational use(s) discussed in this presentation, and no conclusions can or should be drawn regarding the safety or effectiveness of the products for these uses.

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Four Therapeutic Area Pillars Driving Long-term Growth

GENERAL
MEDICINE



ONCOLOGY



INFLAMMATION



RARE DISEASE



Marketed Products
Innovative Pipeline
Biosimilars



Rocatinlimab ROCKET Phase 3 Program Update

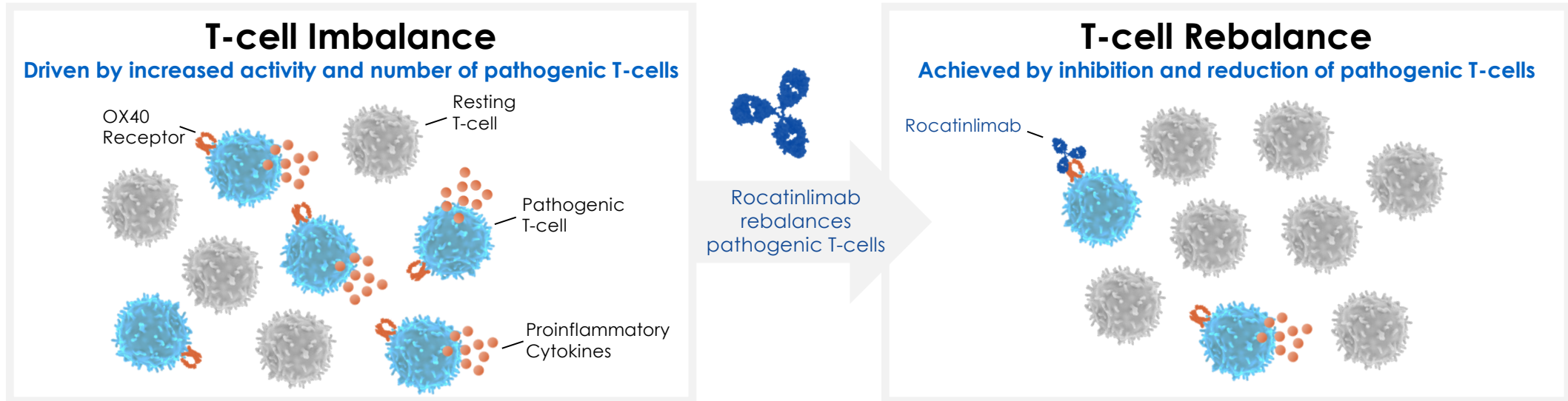


Atopic Dermatitis (AD) Impacts Over 30 Million Individuals Globally

- AD is complex and heterogeneous, presenting with a broad range of symptoms that significantly affects patients' quality of life
 - Impacts ~15%–20% of children and up to 10% of adults in the U.S.
 - Approximately 40% of U.S. adults with AD experience moderate to severe disease
- Over 50% of patients with moderate to severe AD have inadequately controlled disease, even with current therapies, including existing biologics



Rocatinlimab Rebalances T-cells by Targeting OX40 Receptor



- T-cell imbalance is a root cause of inflammatory disease
- Atopic dermatitis is driven in part by the proliferation of pathogenic T-cells
- Rocatinlimab has the potential to inhibit and reduce pathogenic T-cells across heterogeneous patient types by targeting OX40 receptor

ROCKET Phase 3 Program in Atopic Dermatitis Well Underway with Potential in Other Diseases



Moderate to Severe ATOPIC DERMATITIS
Phase 3

Adult

HORIZON: placebo-controlled monotherapy rocatinlimab (N = 726)

IGNITE: placebo-controlled monotherapy evaluating two rocatinlimab doses (N = 769)

SHUTTLE: placebo-controlled trial evaluating two rocatinlimab doses with topical therapy (N = 746)

VOYAGER: placebo-controlled trial assessing vaccine antibody response while on rocatinlimab (N = 221)

Adolescent

ASTRO: 52-week trial evaluating two rocatinlimab doses (N = 500)

ORBIT: 52-week adolescent open-label trial (N = 187)

Adult & Adolescent

ASCEND: maintenance trial with re-randomized withdrawal & extension cohorts (N = 2,200)

OUTPOST: 52-week open label trial of self-administered rocatinlimab (N = 100)

PRURIGO NODULARIS
Phase 3

Adult & Adolescent

Phase 3 trial in prurigo nodularis

ASTHMA
Phase 2

Adult & Adolescent

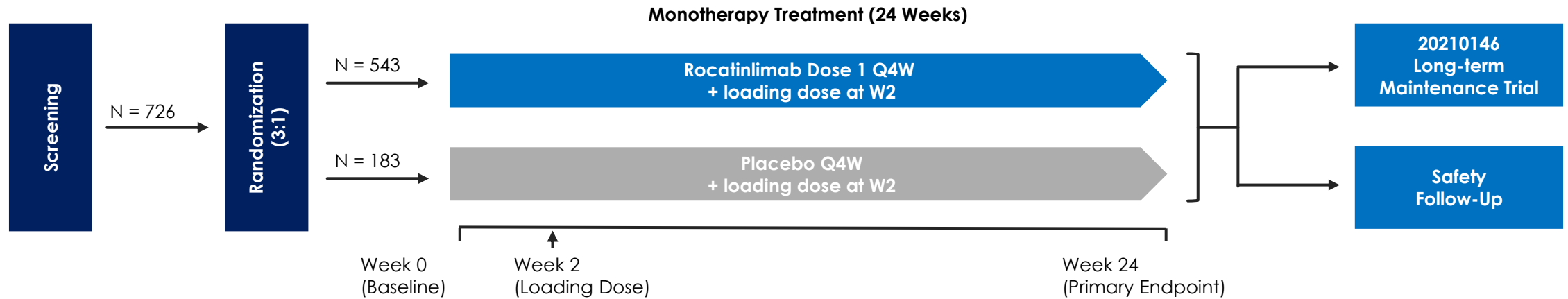
Phase 2 trial in moderate-to-severe asthma

Rocatinlimab, formerly AMG 451/KHK4083, is being developed in collaboration with Kyowa Kirin.

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HORIZON Phase 3 Trial: Investigation of Rocatinlimab in Atopic Dermatitis (AD)



KEY ELIGIBILITY CRITERIA

- ≥ 18 yo, M2S AD
- vIGA-AD 3 or 4
- EASI ≥ 16
- BSA ≥ 10%
- 7-day recall worst pruritus NRS ≥ 4
- Topical failure; bio experienced included

KEY DESIGN CONSIDERATIONS

Rescue therapy was allowed, if deemed necessary

- Subjects who used rescue therapy were considered non responders
- Study treatment was to be discontinued if systemic rescue therapy for AD was used (except for corticosteroids used for ≤ 14 days)

Stratification:

- vIGA-AD 3 vs. vIGA-AD 4
- Japan vs. Non-Japan Asian countries vs. RoW

Q4W = every 4 weeks; W2 = week 2; M2S AD = moderate-to-severe atopic dermatitis; vIGA-AD = Validated Investigator Global Assessment for Atopic Dermatitis; EASI = Eczema Area and Severity Index; BSA = body surface area; NRS = numerical rating scale; RoW = rest of world. Rocatinlimab, formerly AMG 451/KHK4083, is being developed in collaboration with Kyowa Kirin.

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HORIZON Phase 3 Trial: Primary & Key Secondary Endpoints

- **Co-primary endpoint:**

- For US: EASI-75 and rIGA 0/1 at week 24
- Ex-US: EASI-75 and vIGA-AD 0/1 at week 24

- **Key secondary endpoints included:**

- vIGA-AD 0/1 at week 16
- EASI-75 at week 16
- EASI-90 at week 24
- \geq 4-point reduction in worst pruritus NRS at week 24 and week 16
- \geq 4-point reduction in AD skin pain NRS at week 24 and week 16
- \geq 4-point reduction in DLQI at week 24
- Hand clearance at week 24
- Facial clearance at week 24

- **EASI 75:** \geq 75% improvement in the Eczema Area and Severity Index (EASI), a detailed and objective measure that quantifies the extent and severity of atopic dermatitis lesions across four body regions
- **Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD™):**
a simplified, subjective 5-point (0-4) clinician assessment of the overall severity of atopic dermatitis, focusing on a global evaluation of skin appearance, including lesions, redness, and scaling without region-specific detail
- **Revised Investigator Global Assessment (rIGA 0/1):**
a more stringent measure of efficacy than vIGA-AD 0/1 based on its narrower definition of 1 (almost clear)

EASI = Eczema Area and Severity Index; vIGA-AD = Validated Investigator Global Assessment for Atopic Dermatitis; rIGA = Revised Investigator Global Assessment; NRS = numerical rating scale; AD = atopic dermatitis; DLQI = Dermatology Life Quality Index.

Rocafinlimab, formerly AMG 451/KHK4083, is being developed in collaboration with Kyowa Kirin.

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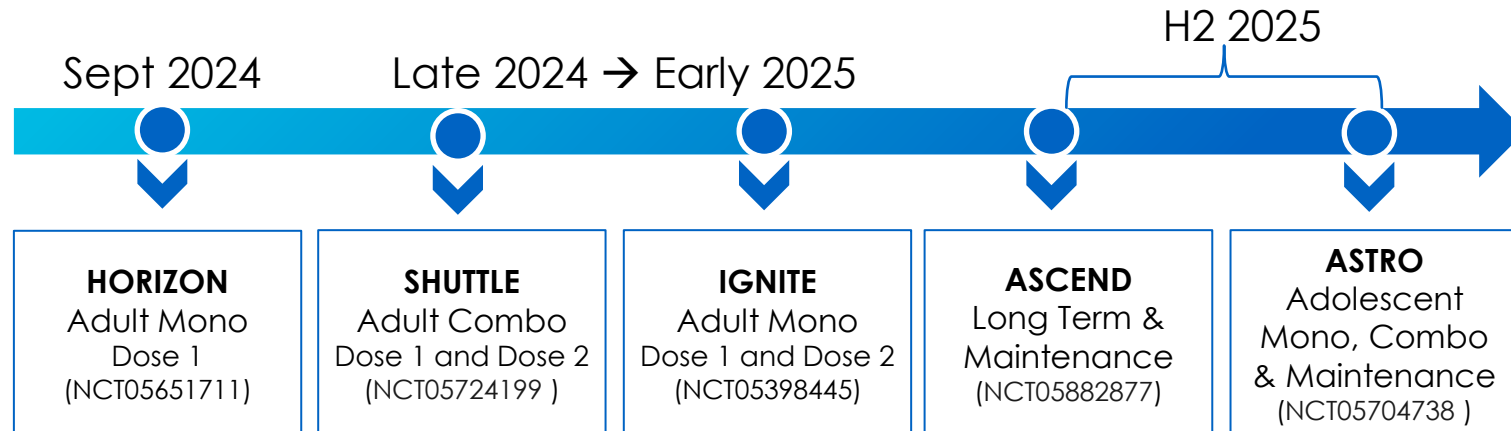
HORIZON Phase 3 Trial: Summary of Results

- Statistically significant improvement observed in co-primary endpoints:
 - 32.8% of rocatinlimab treated subjects achieved an EASI-75 response at week 24 vs. 13.7% placebo (19.1% difference, $p < 0.001$)
 - 19.3% of rocatinlimab treated subjects achieved a vIGA-AD 0/1 response at week 24 vs. 6.6% placebo (12.8% difference, $p < 0.001$)
 - 16.4% of rocatinlimab treated subjects achieved a rIGA 0/1 response at week 24 vs. 4.9% placebo (11.5% difference, $p < 0.001$)
- All key secondary endpoints met statistical significance
- Overall safety results comparable to the Phase 2b trial

The Robust ROCKET Phase 3 Program Is Designed to Provide a Complete Understanding of Rocatinlimab's Profile

- The **HORIZON trial** readout is the **first of eight** pivotal study readouts in atopic dermatitis, building our understanding of rocatinlimab's profile
- We continue to pursue studies in asthma and prurigo nodularis

Key Upcoming ROCKET Phase 3 Program Readouts



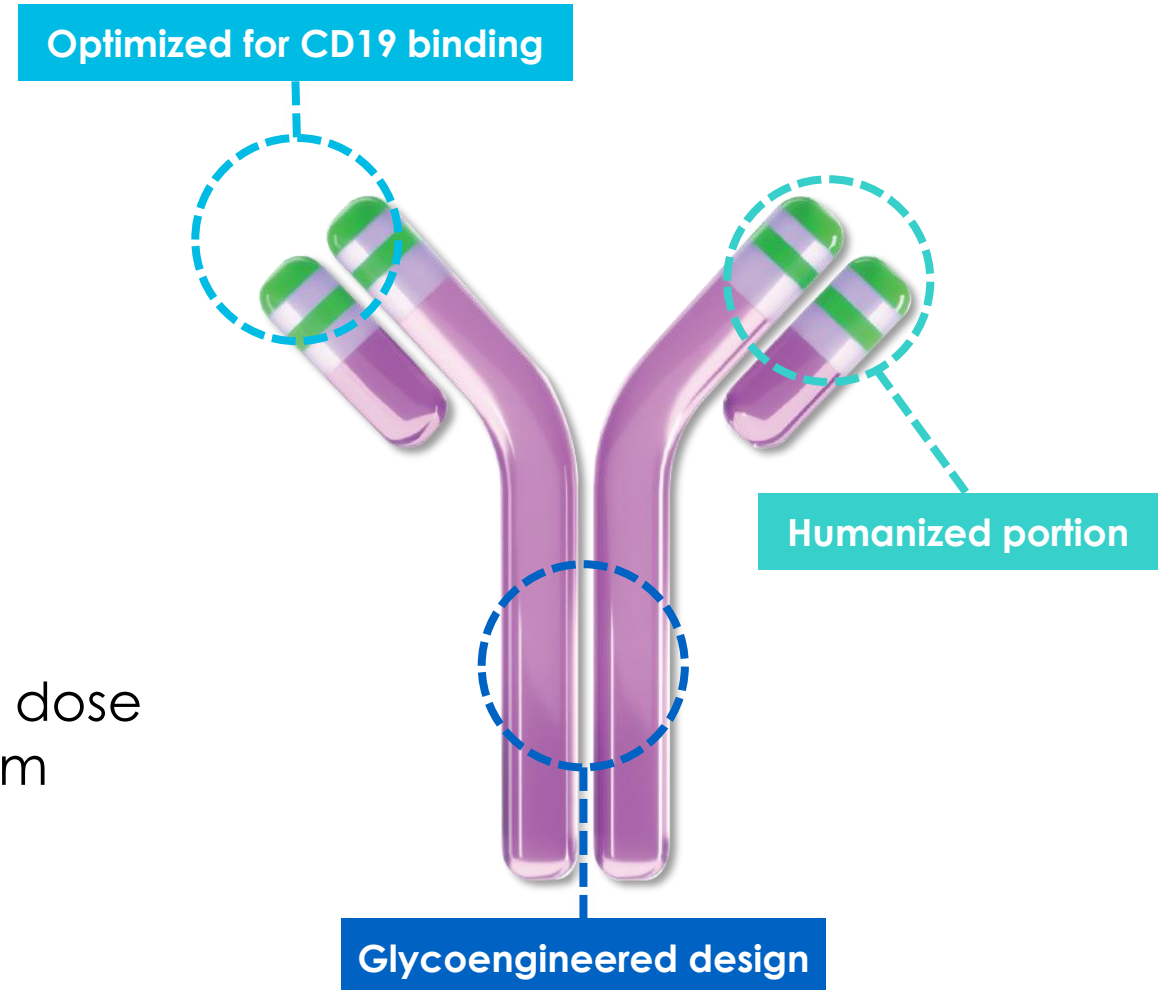
UPLIZNA[®] (inebilizumab-cdon)
Update IgG4 Related Disease
Generalized Myasthenia Gravis

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UPLIZNA® Is an Anti-CD19, Humanized Monoclonal Antibody



- CD19 targeted agent with potential in multiple autoimmune diseases
 - Glycoengineered design to provide efficacy in those that may have diminished responses to other monoclonal antibodies
- Provides targeted, rapid, and sustained CD19+ B-cell depletion—including plasmablasts and certain plasma cells that anti-CD20 therapies do not target
- Convenient 6-month dosing interval after initial dose minimizes patient impact and enables long-term adherence
- Currently approved for AQP4+ NMOSD in the U.S. and countries around the world



IgG4-Related Disease Is a Serious Illness Often Resulting in Permanent Organ Damage

Characteristics and Symptoms

- Chronic, debilitating rare disease characterized by tumor-like inflammatory and fibrotic mass formation in affected organs
 - Specific symptoms depend on which organs are affected; multiple organ involvement is typical
 - Major causes for mortality include liver cirrhosis, portal hypertension, retroperitoneal fibrosis, and other severe organ complications
- U.S. prevalence: ~20K¹
- Significant unmet need; potential to be first FDA-approved therapy

IgG4-Related Disease is Caused by Multiple Mechanisms of B-Cell Dysfunction



IgG4-RD = Immunoglobulin G4-related disease; FDA = U.S. Food and Drug Administration.

1. Source: Wallace ZS et al. Ann Rheum Dis. 2023 Jul;82(7):957-962.

Image source: Stone JH, Zen Y, Deshpande V. IgG4-related disease. N Engl J Med 2012; 366:539

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Landmark MITIGATE Phase 3 Trial Demonstrated Impressive Results in IgG4-RD; Granted Breakthrough Therapy Designation by FDA



- First global placebo controlled, randomized controlled trial in IgG4-RD.
- Met primary endpoint, demonstrating a clinically meaningful and statistically significant **87% reduction** in IgG4-RD flare risk at 52-weeks
 - Compared to placebo (**HR = 0.13, p < 0.0001**)
- All three key secondary endpoints met statistical significance after multiplicity adjustment
- Convenient 6-month dosing interval after initial dose
- Steroid-sparing study design to reduce steroid burden and toxicity
- No new safety signals were identified
- Regulatory filing activities underway

Evaluating UPLIZNA® to Address Unmet Needs in a Broad Generalized Myasthenia Gravis Patient Population



- gMG is a chronic, rare autoimmune neuromuscular disorder
 - Two main types of gMG: AChR+ and MuSK+
- Symptoms include weakness in voluntary muscles, especially those that control the eyes, mouth, throat, and limbs
- Prevalence: ~80K–100K in the U.S.¹
- UPLIZNA® provides potential for differentiation to address unmet needs based on unique MOA and convenient, 6-month dosing after initial dose
- Established safety and tolerability profile in other neurological condition (NMOSD)



**Common gMG Symptom:
Drooping Eyelids (Ptosis)**

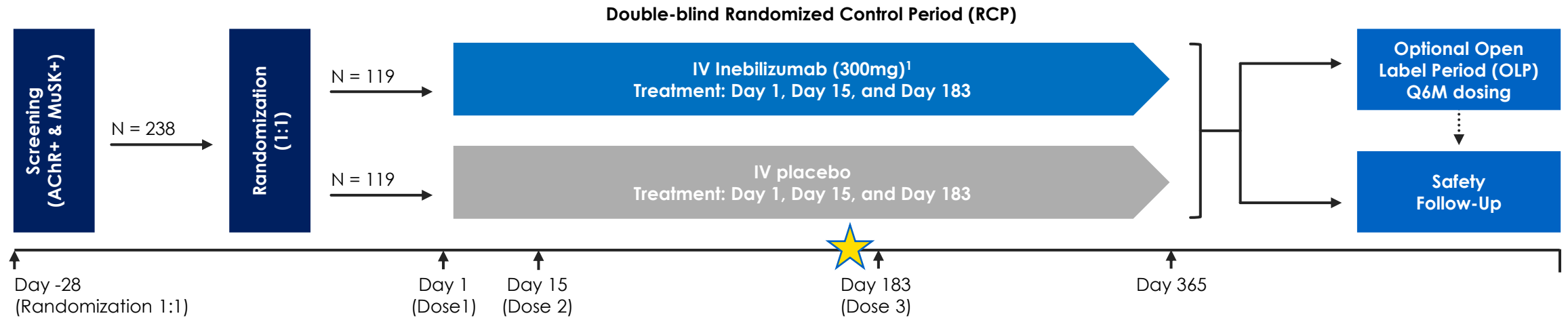
gMG = generalized myasthenia gravis; AChR+ = acetylcholine receptor; MuSK+ = muscle-specific kinase; MOA = mechanism of action; NMOSD = neuromyelitis optica spectrum disorder.

1. Source: Ye et al, *Frontiers in Neurology* Feb 2024; Rodrigues et al, *Muscle and Nerve*, 2023: 1-6.

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MINT: A Phase 3 Trial of UPLIZNA[®] in Generalized Myasthenia Gravis (gMG)



PRIMARY ENDPOINT

Change from baseline in MG-ADL score at Week 26 in the overall study population (i.e., the AChR+ and MuSK+ populations)

KEY INCLUSION CRITERIA

- Diagnosis of gMG with anti-AChR+ or anti-MuSK
- MGFA Clinical Classification Class II, III, or IV
- MG-ADL score of 6 or greater at screening and at randomization with > 50% of this score attributed to non-ocular items
- QMG score of 11 or greater
- Restrictions on use of corticosteroids or allowed non-steroidal immunosuppressive therapies (IST), alone or in combination

KEY DESIGN CONSIDERATIONS

Largest placebo-controlled Generalized Myasthenia Gravis trial for a biologic therapy (238 adults); enrolled largest number of MuSK+ patients (48 adults)

Starting on week 4 visit, all patient who are on corticosteroids will undergo **protocol specified taper** to ≤ 5mg per day **by week 24**

Stratification:

- AChR+, MuSK+

Potential Practice-Changing Phase 3 Results in Generalized Myasthenia Gravis from MINT Trial



- Clinically meaningful and statistically significant MG-ADL score improvement after two doses of UPLIZNA[®] compared to placebo at Week 26: -4.2 overall improvement, -1.9 placebo adjusted ($p < 0.0001$, primary endpoint)
- Achieved clinically meaningful and statistically significant benefit in change in MG-ADL score for both AChR+ and MuSK+ cohorts
- Demonstrated a statistically significant QMG score improvement with UPLIZNA[®] compared to placebo at week 26: -4.8 overall improvement, -2.5 placebo adjusted ($p = 0.0002$, secondary endpoint)
- Assessment of additional efficacy, durability of response and safety ongoing per protocol
- No new safety signals were identified
- Initiating Regulatory filing activities

HIGHLY EFFECTIVE IN GENERALIZED MYASTHENIA GRAVIS WITH PATIENT CENTERED CONVENIENT DOSING AND POTENTIAL TO REDUCE THE USE OF STEROIDS

Questions?

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