# EUROPEAN COMMISSION APPROVES AMGEN'S UPLIZNA® FOR GENERALIZED MYASTHENIA GRAVIS

February 12, 2026

**First and Only CD19-Targeted Therapy Approved in Europe for Adults with anti-AChR+ and anti-MuSK+ gMG**

**UPLIZNA Demonstrates Durable Disease Control with Twice-Yearly Dosing***

THOUSAND OAKS, Calif., Feb. 12, 2026 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced the European Commission (EC) has approved UPLIZNA® (inebilizumab) as an add-on treatment to standard therapy for adults living with generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive. The approval offers patients a new, targeted treatment option with the potential for long-term disease control through twice-yearly maintenance dosing, following two initial loading doses.

Generalized myasthenia gravis is a rare, unpredictable, chronic, B-cell-mediated autoimmune disease that causes fluctuating muscle weakness and can impact quality of life.1-3 It is a subtype of myasthenia gravis (MG), which affects an estimated 56,000-123,000 people in Europe.4

"This approval represents an important advancement for adults with gMG in Europe, helping address debilitating symptoms and potentially reduce the long-term use of steroids where clinically appropriate," said Cesar Sanz Rodriguez, vice president of Medical Affairs at Amgen. "With convenient twice-yearly dosing and durable efficacy in people with anti-AChR and anti-MuSK antibody positive gMG, UPLIZNA brings a new first-in-class approach to managing this complex disease."

The EC approval is supported by data from the Myasthenia Gravis Inebilizumab Trial (MINT), the largest Phase 3 biologic study to include both AChR+ and MuSK+ patients, and the first to successfully incorporate a structured steroid-tapering protocol. Patients receiving steroids at baseline began tapering at Week 4 with a goal of reaching prednisone 5 mg per day by Week 24. By Week 26, 87.4% of patients taking UPLIZNA and 84.6% of those taking placebo had reduced their steroid dose to 5 mg or less per day.5

"UPLIZNA offers a new approach to treating gMG by selectively targeting CD19-positive B cells, which play a key role in disease pathology," said John Vissing, MD, DMSci, professor of neurology and director of the Copenhagen Neuromuscular Center, Rigshospitalet, at the University of Copenhagen. "The approval provides both clinicians and patients a valuable new treatment option with the potential for long-term efficacy while addressing the challenges of long-term steroid exposure."

The approval in gMG builds on UPLIZNA's established efficacy in rare autoimmune conditions, including its November 2025 EC approval as the first and only treatment for adults living with active immunoglobulin G4-related disease (IgG4-RD),6 a chronic and debilitating immune-mediated inflammatory condition that can affect multiple organs.7,8 UPLIZNA was also previously approved as a monotherapy for adult patients with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive.6

UPLIZNA has received regulatory approvals across multiple indications from the U.S. Food and Drug Administration, Health Canada, and the Brazilian Health Regulatory Agency (ANVISA), among others.

**About the MINT Trial**
MINT is a randomized, double-blind, placebo-controlled, parallel-group trial (NCT04524273) designed to evaluate the efficacy and safety of UPLIZNA in adults with gMG. The trial enrolled 238 adults with gMG, including 190 patients who are AChR+ and 48 patients who are MuSK+.5

Eligibility criteria at screening and randomization included a Myasthenia Gravis Foundation of America (MGFA) classification of II, III or IV disease, MG-ADL score between 6 and 10 with greater than 50% of this score attributed to non-ocular items, or an MG-ADL score of at least 11, and a Quantitative Myasthenia Gravis (QMG) score of at least 11.5 Participants had to have been receiving a stable dose of steroids and/or nonsteroidal immunosuppressive therapy (or both) at the time of randomization.5

The primary endpoint was change from baseline in MG-ADL score at Week 26 in the combined study population.5 Key secondary endpoints included change from baseline in QMG scores in the combined study population; change from baseline in MG-ADL score at Week 26 for the AChR+ cohort and separately the MuSK+ cohort; and change from baseline in QMG score at Week 26 for the AChR+ cohort and separately the MuSK+ cohort.5 MINT also includes an optional three-year open-label treatment period.

Key findings from MINT include5:

*Primary Endpoint:*

- A 1.9-point difference in the MG-ADL score for UPLIZNA (-4.2) compared to placebo (-2.2) ($p<0.0001$) at Week 26 for the combined study population.

*Key Secondary Endpoints:*

- A 2.5-point difference in the QMG score for UPLIZNA (-4.8) compared to placebo (-2.3) ($p=0.0002$) at Week 26 for the combined treated population.
- A 1.8-point difference in the MG-ADL score for UPLIZNA (-4.2) compared to placebo (-2.4) ($p=0.0015$) at Week 26 for the AChR+ population.
- A 2.5-point difference in the QMG score for UPLIZNA (-4.4) compared to placebo (-2.0) ($p=0.0011$) at Week 26 for the AChR+ population.

- A 2.2-point difference in the MG-ADL score for UPLIZNA (-3.9) compared to placebo (-1.7) (p=0.0297) at Week 26 for the MuSK+ population.
- A 2.3-point difference in the QMG score for UPLIZNA (-5.2) compared to placebo (-3.0) (p=0.1326) at Week 26 for the MuSK+ population; this difference was not statistically significant.

*Additional Exploratory Endpoints:*

- A 2.8-point difference (95% CI: −3.9 to −1.7) in the MG-ADL score for UPLIZNA (-4.7) compared with placebo (-1.9) at Week 52 for the AChR+ population.
- A 4.3-point difference (95% CI: −5.9 to −2.8) in the QMG score for UPLIZNA (-5.8) compared with placebo (-1.4) at Week 52 for the AChR+ population.
- 87.4% of UPLIZNA patients and 84.6% of those taking placebo reduced their steroid dose to 5 mg or less per day by Week 26.

MG-ADL scale, which assesses the impact of gMG on daily functions of 8 signs or symptoms that are typically affected in gMG. Each item is assessed on a 4-point scale, where a score of 0 represents normal function and a score of 3 represents loss of ability to perform that function. The total MG-ADL score ranges from 0 to 24, with higher scores indicating more impairment.

The QMG score is a 13-item categorical grading system that quantitively measures disease impairment by mainly assessing muscle weakness. Each item is assessed on a 4-point scale where a score of 0 represents no impairment weakness and a score of 3 represents severe impairment weakness. A total possible score ranges from 0 to 39, where higher scores indicate more severe impairment.

**About Generalized Myasthenia Gravis (gMG)**
Generalized myasthenia gravis (gMG) is a rare, chronic, B-cell-mediated autoimmune disorder that impairs neuromuscular communication and can cause muscle weakness, trouble breathing, difficulty swallowing and impaired speech and vision.1-3

Approximately 85% of patients with myasthenia gravis have the generalized form, or gMG.9,10 The prevalence and incidence of gMG are increasing worldwide.10 There are an estimated 56,000 to 123,000 people with myasthenia gravis in Europe, with prevalence rates in different countries varying significantly.4 Approximately 85% of patients with myasthenia gravis have detectable antibodies against AChR, and approximately 7% have detectable antibodies against MuSK.11 Global prevalence is estimated at 2-36 cases per 100,000.4 The disease is more frequently seen in young women (age 20-30) and men aged 50 years and older.4,10

B cells are central to the pathogenesis of gMG. The disease is thought to be primarily driven by pathogenic CD19+ plasmablasts and plasma cells that target critical proteins in the neuromuscular junction.1-3

**About UPLIZNA® (inebilizumab)**
UPLIZNA is a humanized monoclonal antibody (mAb) that causes targeted and sustained depletion of key cells that contribute to the underlying disease process (autoantibody-producing CD19+ B cells, including plasmablasts and some plasma cells). The precise mechanism by which UPLIZNA exerts its therapeutic effects is unknown. After two initial infusions, patients need one maintenance dose of UPLIZNA every six months.

**About Amgen**
Amgen discovers, develops, manufactures and delivers innovative medicines to fight some of the world's toughest diseases. Harnessing the best of biology and technology, Amgen reaches millions of patients with its medicines.

More than 45 years ago, Amgen helped establish the biotechnology industry at its U.S. headquarters in Thousand Oaks, California, and it remains at the cutting edge of innovation, using technology and human genetic data to push beyond what is known today. Amgen is advancing a broad and deep pipeline and portfolio of medicines to treat cancer, heart disease, inflammatory conditions, rare diseases and obesity and obesity-related conditions.

Amgen has been consistently recognized for innovation and workplace culture, including honors from Fast Company and Forbes. Amgen is one of the 30 companies that comprise the Dow Jones Industrial Average®, and it is also part of the Nasdaq-100 Index®, which includes the largest and most innovative non-financial companies listed on the Nasdaq Stock Market based on market capitalization.

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**Amgen Forward-Looking Statements**
This news release contains forward-looking statements that are based on the current expectations and beliefs of Amgen. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including any statements on the outcome, benefits and synergies of collaborations, or potential collaborations, with any other company (including BeOne Medicines Ltd. or Kyowa Kirin Co., Ltd.), the performance of Otezla® (apremilast), our acquisitions of ChemoCentryx, Inc., Dark Blue Therapeutics, Ltd. or Horizon Therapeutics plc (including the prospective performance and outlook of Horizon's business, performance and opportunities, and any potential strategic benefits, synergies or opportunities expected as a result of such acquisition), as well as estimates of revenues, operating margins, capital expenditures, cash, other financial metrics, expected legal, arbitration, political, regulatory or clinical results or practices, customer and prescriber patterns or practices, reimbursement activities and outcomes, effects of pandemics or other widespread health problems on our business, outcomes, progress and other such estimates and results. Forward-looking statements involve significant risks and uncertainties, including those discussed below and more fully described in the Securities and Exchange Commission reports filed by Amgen, including our most recent annual report on Form 10-K and any subsequent periodic reports on Form 10-Q and current reports on Form 8-K. Unless otherwise noted, Amgen is providing this information as of the date of this news release and does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise.

No forward-looking statement can be guaranteed and actual results may differ materially from those we project. 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, including those resulting from geopolitical relations and government actions. 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. We or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market. 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. 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, 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. Discovery or identification of new product candidates or development of new indications for existing products cannot be guaranteed and movement from concept to product is uncertain; consequently, there can be no guarantee that any particular product candidate or development of a new indication for an existing product will be successful and become a commercial product. 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, and may result in unanticipated costs, delays or failures to realize the benefits of the transactions. 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 sustainability 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.

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**References**

**After two initial loading doses.*

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