



## FDA APPROVES UPLIZNA® FOR ADULTS WITH GENERALIZED MYASTHENIA GRAVIS

December 11, 2025

### UPLIZNA Offers gMG Patients Deep and Durable Symptom Control and Twice-Yearly Dosing\*

#### First and Only CD19-Targeted B Cell Therapy Approved in anti-AChR and anti-MuSK Ab+ gMG

THOUSAND OAKS, Calif., Dec. 11, 2025 /PRNewswire/ -- Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved UPLIZNA® (inebilizumab-cdon) for the treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) and anti-muscle specific tyrosine kinase (MuSK) antibody positive. The approval offers patients a new targeted treatment option that has the potential for long-term disease control with just two doses a year, after two initial loading doses.

"This approval marks a significant advancement for people living with gMG," said Jay Bradner, M.D., executive vice president of Research and Development at Amgen. "By selectively targeting CD19-positive B cells, UPLIZNA offers a new approach to treatment that addresses a biological root cause of disease. UPLIZNA is conveniently dosed twice a year and delivers durable efficacy, helping people manage debilitating symptoms that can compromise daily function – including trouble breathing, speaking and seeing."

gMG is a rare, unpredictable, chronic, B-cell-mediated autoimmune disorder that impairs neuromuscular communication and can cause fluctuating muscle weakness.<sup>1-3</sup> The disease is thought to be primarily driven by AChR and MuSK autoantibodies, which are produced by CD19+ B cells, particularly plasmablasts and some plasma cells.<sup>1-3</sup> Myasthenia gravis impacts approximately 80,000 to 100,000 people in the U.S.<sup>4,5</sup>

The approval of UPLIZNA for gMG 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 steroid taper into its protocol. Patients on steroids at baseline began tapering at Week 4 to reach 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.<sup>6</sup>

"UPLIZNA showed strong efficacy at 26 weeks in both AChR+ and MuSK+ patients, with AChR+ patients continuing to improve through 52 weeks in MINT," said Richard J. Nowak, M.D., M.S., global principal investigator and director of the Myasthenia Gravis Clinic at Yale University. "MINT also uniquely required steroid tapering, recognizing that long-term steroid use adds to the overall burden of disease. This approval brings a new first-in-class approach to gMG, expanding treatment options for clinicians and patients."

At Week 26, UPLIZNA demonstrated a 1.9-point difference in the Myasthenia Gravis Activities of Daily Living (MG-ADL) score compared with placebo (-4.2 vs. -2.2;  $p < 0.0001$ ).<sup>6</sup> Benefits in the AChR+ patient subgroup continued through Week 52 – the longest randomized-controlled period for a Phase 3 trial in gMG – with an exploratory analysis of AChR+ patients showing a 2.8-point difference in MG-ADL for UPLIZNA compared with placebo (-4.7 vs. -1.9; 95% CI: -3.9 to -1.7).<sup>6</sup>

"Managing a rare and chronic illness can mean facing unpredictable relapsing symptoms and demanding treatment schedules," said Samantha Masterson, president and chief executive officer of the Myasthenia Gravis Foundation of America. "This approval marks an important milestone, offering durable efficacy and a dosing schedule that provides people living with generalized myasthenia gravis six months of treatment-free time between maintenance doses."

This is the third indication for UPLIZNA, which was previously approved by the FDA for the treatment of adult patients with anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD) in June 2020, and for the treatment of adult patients with Immunoglobulin G4-related disease (IgG4-RD) in April 2025.

The most common adverse reactions in gMG were headache and infusion-related reactions.<sup>7</sup>

Amgen is committed to supporting patients with gMG and helping appropriate patients with access to UPLIZNA. Patients and caregivers who need support, tools, or resources can contact [Amgen By Your Side](#).

\*After two initial loading doses.

#### About the Myasthenia Gravis Inebilizumab Trial (MINT)

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+.<sup>6</sup>

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.<sup>6</sup> Participants had to have been receiving a stable dose of steroids and/or nonsteroidal immunosuppressive therapy (or both) at the time of randomization.<sup>6</sup>

The primary endpoint was change from baseline in MG-ADL score at Week 26 in the combined study population.<sup>6</sup> 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.<sup>6</sup> MINT also includes an optional three-year open-label treatment period.

Key findings from MINT include:<sup>6</sup>

*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 quantitatively 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)**

gMG is a rare, unpredictable, chronic, B-cell-mediated autoimmune disorder that impairs neuromuscular communication and can cause fluctuating muscle weakness, trouble breathing, difficulty swallowing, and impaired speech and vision.<sup>1-3</sup>

Approximately 85% of patients with myasthenia gravis have the generalized form, or gMG.<sup>8,9</sup> The prevalence and incidence of gMG are increasing worldwide.<sup>9</sup> There are between 80,000 and 100,000 patients with myasthenia gravis in the U.S.<sup>4,5</sup> Approximately 85% of patients with myasthenia gravis have detectable antibodies against AChR, and approximately 7% have detectable antibodies against MuSK.<sup>10</sup> Global prevalence is estimated at 2-36 cases per 100,000.<sup>11</sup> The disease is more frequently seen in young women (age 20-30) and men aged 50 years and older.<sup>9,11</sup>

B cells are central to the pathogenesis of gMG. The disease is thought to be primarily driven by AChR and MuSK autoantibodies which are produced by CD19+ B cells, particularly plasmablasts and some plasma cells. These antibodies target and disrupt critical proteins in the neuromuscular junction.<sup>1-3</sup>

**About UPLIZNA® (inebilizumab-cdon)**

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

**UPLIZNA® (inebilizumab-cdon) U.S. INDICATION**

**INDICATIONS**

UPLIZNA® (inebilizumab-cdon) is indicated in adult patients for the treatment of: anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD); Immunoglobulin G4-related disease (IgG4-RD); anti-acetylcholine receptor (AChR) or anti-muscle specific tyrosine kinase (MuSK) antibody positive (Ab+) generalized myasthenia gravis (gMG).

**IMPORTANT SAFETY INFORMATION**

**CONTRAINDICATIONS**

UPLIZNA® (inebilizumab-cdon) is contraindicated in patients with a history of a life-threatening infusion reaction to UPLIZNA, active hepatitis B infection, or active or untreated latent tuberculosis.

**WARNINGS AND PRECAUTIONS**

- **Infusion Reactions:** Infusion reactions, including anaphylaxis, can occur. Symptoms can include headache, nausea, somnolence, dyspnea, fever, myalgia, rash, or palpitations. Infusion reactions were observed in 9.3%, 7.4%, and 10.1% of patients treated with UPLIZNA during the randomized controlled periods (RCPs) of Study 1 in patients with NMOSD, Study

2 in patients with IgG4-RD, and Study 3 in patients with gMG, respectively. Infusion reactions were most common with the first infusion but were also observed during subsequent infusions.

Administer pre-medication with a corticosteroid, an antihistamine, and an antipyretic. For life-threatening infusion reactions, immediately and permanently stop UPLIZNA and administer appropriate supportive treatment. For less severe infusion reactions, management may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

- **Infections:** Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with B-cell depleting therapies, including UPLIZNA. The most common infections reported by UPLIZNA-treated patients in the NMOSD randomized and open-label clinical trial periods for NMOSD were urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). In the IgG4-RD RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection, influenza, and pneumonia. In the gMG RCP, the most common infections reported by UPLIZNA-treated patients were urinary tract infection and nasopharyngitis. Delay UPLIZNA administration in patients with an active infection until the infection is resolved.

Possible Increased Risk of Immunosuppressant Effects with Other Immunosuppressants: If combining UPLIZNA with another immunosuppressive therapy, consider the potential for increased immunosuppressive effects.

Hepatitis B Virus (HBV) Reactivation: HBV reactivation has been observed with B-cell-depleting therapies, including UPLIZNA. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with B-cell depleting therapies. HBV reactivation was observed in a patient treated with UPLIZNA during the gMG clinical trial and in the postmarketing setting. Patients with active or chronic HBV infection were excluded from clinical trials. Perform HBV screening in all patients before initiation of treatment. Do not administer to patients with active HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for HBsAg and positive for HBcAb, or who are carriers of HBV (i.e., HBsAg+), consult liver disease experts before starting and during treatment.

Progressive Multifocal Leukoencephalopathy (PML): Although no confirmed cases of PML were identified in UPLIZNA clinical trials, JC virus infection resulting in PML has been observed in patients treated with other B-cell-depleting antibodies and other therapies that affect immune competence. In UPLIZNA clinical trials one subject died following the development of new brain lesions for which a definitive diagnosis could not be established, though the differential diagnosis included an atypical NMOSD relapse, PML, or acute disseminated encephalomyelitis. At the first sign or symptom suggestive of PML, withhold UPLIZNA and perform an appropriate diagnostic evaluation. MRI findings may be apparent before clinical signs or symptoms. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

#### Tuberculosis

Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating UPLIZNA. Consider anti-tuberculosis therapy prior to initiation of UPLIZNA in patients with a history of latent active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Consult infectious disease experts regarding whether initiating anti-tuberculosis therapy is appropriate before starting treatment.

#### Vaccinations

Administer all immunizations according to immunization guidelines at least 4 weeks prior to initiation of UPLIZNA. The safety of immunization with live or live-attenuated vaccines following UPLIZNA therapy has not been studied, and vaccination with live-attenuated or live vaccines is not recommended during treatment and until B-cell repletion.

#### *Vaccination of Infants Born to Mothers Treated with UPLIZNA During Pregnancy*

In infants of mothers exposed to UPLIZNA during pregnancy, do not administer live or live-attenuated vaccines before confirming recovery of B-cell counts in the infant. Depletion of B cells in these exposed infants may increase the risks from live or live-attenuated vaccines. Non-live vaccines, as indicated, may be administered prior to recovery from B-cell and immunoglobulin level depletion, but consultation with a qualified specialist should be considered to assess whether a protective immune response was mounted.

- **Reductions in Immunoglobulins:** There may be a progressive and prolonged hypogammaglobulinemia or decline in the levels of total and individual immunoglobulins such as immunoglobulins G and M (IgG and IgM) with continued UPLIZNA treatment. Monitor the levels of quantitative serum immunoglobulins during treatment with UPLIZNA, especially in patients

with opportunistic or recurrent infections, and until B-cell repletion after discontinuation of therapy. Consider discontinuing UPLIZNA therapy if a patient with low immunoglobulin G or M develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.

- **Fetal Risk:** Based on animal data, UPLIZNA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to UPLIZNA even after B-cell repletion. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other B-cell-depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving UPLIZNA and for at least 6 months after the last dose.

## ADVERSE REACTIONS

- The most common adverse reactions (at least 10% of patients treated with UPLIZNA and greater than placebo): urinary tract infection and arthralgia in NMOSD; urinary tract infection and lymphopenia in IgG4-RD; headache and infusion-related reactions in gMG.

[Please see UPLIZNA® full Prescribing Information.](#)

## About Amgen

Amgen discovers, develops, manufactures and delivers innovative medicines to help millions of patients in their fight against some of the world's toughest diseases. More than 40 years ago, Amgen helped to establish the biotechnology industry and remains on the cutting-edge of innovation, using technology and human genetic data to push beyond what's known today. Amgen is advancing a broad and deep pipeline that builds on its existing portfolio of medicines to treat cancer, heart disease, osteoporosis, inflammatory diseases and rare diseases.

In 2024, Amgen was named one of the "World's Most Innovative Companies" by Fast Company and one of "America's Best Large Employers" by Forbes, among other [external recognitions](#). 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. 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. 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, preclinical results do not guarantee safe and effective performance of product candidates in humans. The complexity of the human body cannot be perfectly, or sometimes, even adequately modeled by computer or cell culture systems or animal models. The length of time that it takes for us to complete clinical trials and obtain regulatory approval for product marketing has in the past varied and we expect similar variability in the future. Even when clinical trials are successful, regulatory authorities may question the sufficiency for approval of the trial endpoints we have selected. We develop product candidates internally and through licensing collaborations, partnerships and joint ventures. Product candidates that are derived from relationships may be subject to disputes between the parties or may prove to be not as effective or as safe as we may have believed at the time of entering into such relationship. Also, we or others could identify safety, side effects or manufacturing problems with our products, including our devices, after they are on the market.

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. 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. 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 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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