Tanabe Pharma
Creating hope for all facing illness.

Press Release

September 16, 2026

Tanabe Pharma Receives Approval in Japan for additional indication of generalized Myasthenia Gravis
Anti-CD19 monoclonal antibody UPLIZNA® for I.V. Infusion 100 mg

Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director, CEO: Akihisa Harada; hereinafter "Tanabe Pharma") announced today that it has received approval from Japan's Ministry of Health, Labour and Welfare for an additional indication for UPLIZNA® for intravenous infusion 100 mg (generic name: Inebilizumab (Genetical Recombination), hereinafter "UPLIZNA®") for the treatment of generalized Myasthenia Gravis (gMG) in patients who do not respond adequately to corticosteroids or non-steroidal immunosuppressants. The approval was granted on September 16, 2026.

gMG is a rare, unpredictable, chronic, B-cell-mediated autoimmune disorder that impairs neuromuscular communication and can cause fluctuating muscle weakness.[1)-3)] 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.[1)-3)] gMG can cause fluctuating muscle weakness, trouble breathing, difficulty swallowing, and impaired speech and vision. Other approved treatments for gMG in Japan include corticosteroids, non-steroidal immunosuppressants, and targeted therapies.

UPLIZNA® is an antibody therapy that targets CD19+ B cells responsible for producing autoantibodies. As of the date of approval, UPLIZNA® is the only treatment approved in Japan for gMG with a mechanism of action that targets CD19+ B cells.

The approval of UPLIZNA® was based on data from the Myasthenia Gravis Inebilizumab Trial (MINT)[4)], which is being conducted in collaboration with Amgen Inc., the licensor of UPLIZNA®. MINT is 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.[4)] 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; $p<0.0001$).[4)] 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).[4)]

Tanabe Pharma remains committed to providing patients with medicines that address unmet medical needs, through its own research and development as well as partnerships with other companies.

About UPLIZNA®

UPLIZNA® is a humanized monoclonal antibody 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. However, UPLIZNA® is considered to specifically bind to CD19 and reduce CD19+ B cells, thereby contributing to the suppression of IgG antibody production, including pathogenic IgG autoantibodies. After two initial infusions, patients need one maintenance dose of UPLIZNA® every six months.

In Japan, UPLIZNA® received manufacturing and marketing approval in March 2021 for the indication of “prevention of relapse in neuromyelitis optica spectrum disorder (including neuromyelitis optica)”. In addition, approval of the additional indication of “suppression of relapse in IgG4-related disease” was granted in November 2025.

About Generalized Myasthenia Gravis

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)]

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.[1)-3)]

According to a nationwide epidemiological survey conducted in Japan in 2018, approximately 29,000 patients were estimated to have MG, corresponding to a prevalence of 23.1 per 100,000 population. The median age at disease onset was 59 years, females were affected slightly more frequently than males, and approximately 80% of patients with MG were reported to be gMG.[5)6)]

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 were AChR+ and 48 patients who were MuSK+.[4)]

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. Participants had to have been receiving a stable dose of steroids and/or nonsteroidal immunosuppressive therapy (or both) at the time of randomization.[4)]

The primary endpoint was change from baseline in MG-ADL at Week 26 in the combined study population. 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. MINT also includes an optional three-year open-label treatment period.[4)]

*MG-ADL score 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.[7)]

*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. [7)]

1) Yi JS, et al.: Muscle Nerve. 2018;57(2):172-184
2) Willcox HN, et al.: Clin Exp Immunol. 1984;58:97-106
3) Stathopoulos P, et al.: JCI Insight. 2017;2(17):e94263
4) ClinicalTrials.gov. NCT04524273
5) Suzuki S, et al.: Clin Exp Neuroimmunol. 2023;14:5-12
6) Yoshikawa H, et al.: PLoS One. 2022 Sep 21;17(9):e02741614
7) Wolfe GI, et al.: Neurology. 1999 Apr 22; 52(7): 1487-9

About Tanabe Pharma

Tanabe Pharma Corporation is a Japan-focused, innovation-driven pharmaceutical company guided by its mission, "Creating hope for all facing illness." Founded in 1678, the company is one of Japan's oldest pharmaceutical companies and is committed to addressing unmet medical needs through R&D, business development, and strategic partnerships with the aim of improving the lives of patients.

For more information, visit https://www.tanabe-pharma.com/en/