Mitsubishi Tanabe Pharma

October 14, 2025

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

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director, CEO: Akihisa Harada, "MTPC") filed an application with the Ministry of Health, Labour and Welfare for an additional indication of the anti-CD19 monoclonal antibody UPLIZNA® for intravenous infusion 100mg (generic name: Inebilizumab (Genetical Recombination), hereinafter UPLIZNA) for the treatment of generalized Myasthenia Gravis (gMG) on October 14, 2025.
In gMG, UPLIZNA® was granted Orphan Drug Designation by the Ministry of Health, Labour and Welfare.

gMG is a chronic autoimmune disease involving pathogenic autoantibodies at the neuromuscular junction. It is characterized by generalized muscle weakness affecting the periocular area, eyes, limbs, and respiratory system. Multiple subtypes exist, depending on the specificity of the autoantibodies.
For the treatment of gMG, steroids, non-steroidal immunosuppressants, and molecular targeted drugs have been approved. However, there are currently no approved treatments that directly target B cells, which produce pathogenic autoantibodies.

A Phase 3 multi-regional clinical trial (MINT study) was conducted in collaboration with Amgen Inc., the company that developed UPLIZNA®, to evaluate efficacy and safety of UPLIZNA® in patients with gMG. This application is based on data from the MINT study.

MTPC is working to provide patients with new drugs that address unmet medical needs, including rare diseases, through our own development and through partnerships with other companies.

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About UPLIZNA®
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 patient receives a second dose 14 days after the initial administration, followed by one dose every six months after the first administration.

In Japan, manufacturing and marketing approval was obtained in 2021 for the indication of "prevention of relapse in neuromyelitis optica spectrum disorder (including neuromyelitis optica)", and UPLIZNA® is currently being marketed. An application for an additional indication for IgG4-related disease is currently under review.

About Generalized Myasthenia Gravis

Myasthenia Gravis (MG) is a chronic, rare autoimmune neuromuscular disease in which pathogenic autoantibodies bind to proteins on the postsynaptic membrane at the junction between peripheral nerves and muscles (the neuromuscular junction), resulting in the destruction of receptors on the muscle side. Among them, generalized Myasthenia Gravis (gMG) is characterized by generalized muscle weakness affecting the periocular area, eyes, limbs, and respiratory system. The severity can vary from interfering with daily activities to life-threatening respiratory failure.

According to a nationwide epidemiological survey conducted in Japan in 2018, the number of patients with MG is estimated to be about 29,000, with a prevalence of 23.1 per 100,000 population. The median age of onset is 59 years, the disease is slightly more common in females, and about 80% of cases are reported to be gMG[1) 2)].

1) Two-step nationwide epidemiological survey of myasthenia gravis in Japan 2018
DOI：10.1371/journal.pone.0274161

2) Japan MG registry: Chronological surveys over 10 years
DOI：10.1111/cen3.12731