



March 21, 2025

Mitsubishi Tanabe Pharma Corporation

Anti-CD19 monoclonal antibody UPLIZNA® for I.V. Infusion 100mg
Application for additional indication of
immunoglobulin G4-related disease in Japan

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director: Akihiro Tsujimura; hereinafter, "MTPC") , a member of the Mitsubishi Chemical Group announced today that 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 immunoglobulin G4-related disease (IgG4-RD) on March 19, 2025.

In IgG4-RD, UPLIZNA was granted Orphan Drug Designation by the Ministry of Health, Labour and Welfare and is subject to priority review.

IgG4-RD is a chronic, systemic, immune-mediated, fibroinflammatory disease which can affect numerous and generally multiple organs of the body. It is a progressive disease affecting new organs over time either consecutively or simultaneously and is characterized by periods of remission and unpredictable disease flares.

No therapeutic drugs have been approved in Japan for IgG4-RD. In addition, while steroid therapy is effective, there can be many recurrences of disease and no treatment method at the time of recurrence has been established.

A global Phase 3 clinical study (MITIGATE trial) was conducted in collaboration with Amgen to evaluate the efficacy and safety of UPLIZNA in reducing the risk of flares in patients with IgG4-RD. The application is based on the data of MITIGATE trial.

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 precise mechanism by which UPLIZNA exerts its therapeutic effects is unknown. After two initial infusions, patients need one dose of UPLIZNA every six months.

In Japan, UPLIZNA is indicated for prevention of relapses of neuromyelitis optica spectrum disorder (including neuromyelitis optica).

About IgG4-RD

Immunoglobulin G4-related disease (IgG4-RD) is a chronic, systemic, immune-mediated, fibroinflammatory disease which can affect numerous and generally multiple organs of the body. It is a progressive disease affecting new organs over time either consecutively or simultaneously and is characterized by periods of remission and unpredictable disease flares. IgG4-RD can cause permanent organ damage with or without the presence of symptoms. Awareness of how organ damage manifests is critically important to inform the timely diagnosis of IgG4-RD. B cells are central to the pathogenesis of IgG4-RD. In IgG4-RD, CD19-expressing (CD19+) B cells are thought to drive inflammatory and fibrotic processes and interact with other immune cells that contribute to disease activity.

The prevalence is estimated at 5 in 100,000 worldwide, although the number of IgG4-RD patients is difficult to determine based on limited epidemiology data. The typical age of onset of IgG4-RD is between 50 and 70 years old and, unlike many other immune-mediated diseases, IgG4-RD is more likely to occur in men than women.