Mitsubishi Tanabe Pharma

November 20, 2025

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

～Japan's First Drug Approved for IgG4-Related Disease～

Mitsubishi Tanabe Pharma Corporation (Head Office: Chuo-ku, Osaka; Representative Director, CEO: Akihisa Harada, "MTPC") has obtained the regulatory approval of the anti-CD19 monoclonal antibody UPLIZNA® for intravenous infusion 100mg (generic name: Inebilizumab (Genetical Recombination), hereinafter UPLIZNA) for the treatment of the suppression of relapse of immunoglobulin G4-rellated disease (IgG4-RD) by the Ministry of Health, Labour and Welfare in Japan on November 20, 2025.

IgG4-RD can occur in multiple organs and lead to fibrosis and permanent organ damage[1]. It is a progressive disease that is characterized by periods of remission and unpredictable disease flares[2)3)]. The exact pathogenesis of IgG4-related disease remains unknown, but B-cells, particularly IgG4-positive plasmablasts and plasma cells, might contribute to disease pathogenesis[4]. UPLIZNA is the first pharmaceutical product approved in Japan for IgG4-RD.

A Phase 3 multi-regional clinical study (MITIGATE study) was conducted in collaboration with Amgen Inc., the company that developed UPLIZNA, to evaluate the efficacy and safety of UPLIZNA in patients with IgG4-RD. The approval is based on the data of MITIGATE 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 generalized Myasthenia Gravis is currently under review.

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[1)]. The exact pathogenesis of IgG4-related disease remains unknown, but B-cells, particularly IgG4-positive plasmablasts and plasma cells, might contribute to disease pathogenesis[4)]. It is a progressive disease that can affect a variety of organ system and often affect multiple organs over time. It is characterized by periods of remission and unpredictable disease flares[2)3)]. IgG4-RD can cause permanent organ damage with or without the presence of symptoms[5)]. B cells are central to the pathogenesis of IgG4-RD[1)] 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[1)5)].
The prevalence is estimated at 5 in 100,000 worldwide[1)5)]. The typical age of onset of IgG4-RD is between 50 and 70 years old and, it varies depending on the location of the lesion, IgG4-RD is more likely to occur in men than women[2)].

1) Inebilizumab for Treatment of IgG4-Related Disease.
DOI:10.1056/NEJMoa2409712

2) IgG4-related disease: Changing epidemiology and new thoughts on a multisystem disease.
DOI:10.1016/j.jtauto.2020.100074

3) Predictors of disease relapse in IgG4-related disease following rituximab.
DOI:10.1093/rheumatology/kev438

4) B lymphocytes directly contribute to tissue fibrosis in patients with IgG4-related disease.
DOI:10.1016/j.jaci.2019.07.004

5) IgG4-related disease: an update on pathophysiology and implications for clinical care.
DOI:10.1038/s41584-020-0500-7