

June 26, 2020

**Notification of Marketing Authorization Application  
for Inebilizumab for the Treatment of  
Neuromyelitis Optica Spectrum Disorder in Japan**

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President & Representative Director; Hiroaki Ueno; hereafter, "MTPC") announced today that it has filed an application for marketing authorization with the Ministry of Health, Labour and Welfare for inebilizumab (MT-0551). The application is for an indication of neuromyelitis optica spectrum disorder (NMOSD). Inebilizumab is an anti-CD19 monoclonal antibody of which MTPC obtained license from Viela Bio, Inc. (Head Office: Maryland, U.S.). It was designated as an orphan drug in February 2020.

Inebilizumab is a humanized anti-CD19 monoclonal antibody with high affinity for a protein called CD19 that is expressed on the surface of B cells including antibody-producing plasmablasts and plasma cells. By binding to CD19, inebilizumab rapidly depletes these cells from the circulation.

Inebilizumab has shown good efficacy and safety in a global clinical trial (N-MOMentum) conducted by Viela Bio. The current application by MTPC is based on the data from the N-MOMentum. In the U.S., it was approved for the indication of NMOSD on June 11, 2020 under the name of UPLIZNA™.

NMOSD is a rare, severe, relapsing, autoimmune disease of the central nervous system that can be fatal. In Japan, it has a low prevalence rate of 2 to 4 cases per 100,000 population<sup>1</sup>. The body's immune system reacts against healthy cells (most commonly in the optic nerve, spinal cord and brain), resulting in NMOSD attack and severe damage. It may cause pain in the eye and vision loss, severe muscle weakness and paralysis, numbness, loss of bladder and bowel control and respiratory failure<sup>2</sup>.

MTPC has identified the central nervous system as one of its priority disease areas, and is moving forward aggressively to work to develop new drugs that address unmet medical needs.

<sup>1</sup> Japanese Society of Neurology, 2017 guidelines for the diagnosis and treatment of multiple sclerosis / neuromyelitis optica

<sup>2</sup> National Institute of Neurological Disorders and Stroke, National Institutes of Health  
<https://www.ninds.nih.gov/Disorders/All-Disorders/Neuromyelitis-Optica-Information-Page>

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