



March 23, 2021

Manufacturing and Marketing Approval of UPLIZNA[®] for I.V. Infusion 100mg for the Treatment of Neuromyelitis Optica Spectrum Disorder in Japan

Mitsubishi Tanabe Pharma Corporation (Head Office: Osaka; President & Representative Director; Hiroaki Ueno; hereafter, "MTPC") today announced that it has obtained manufacturing and marketing approval of UPLIZNA[®] for I.V. Infusion 100mg (MT-0551, generic name: inebilizumab (genetically modified), (UPLIZNA)) for the prevention of relapses of neuromyelitis optica spectrum disorder (including neuromyelitis optica) by the Ministry of Health, Labour and Welfare in Japan on March 23, 2021. UPLIZNA is a humanized anti-CD19 monoclonal antibody of which MTPC obtained license from Viela Bio, Inc., which was acquired by Horizon Therapeutics plc on March 15, 2021.

Neuromyelitis Optica Spectrum Disorder (NMOSD) is an autoimmune disease of the central nervous system characterized by severe optic neuritis and transverse myelitis and designated intractable disease. Relapse may occur repeatedly, and a single relapse may lead to vision loss or wheelchair activity.

UPLIZNA binds to a protein called CD19 which is expressed on B cells including antibody-producing plasmablasts and plasma cells, and rapidly depletes these cells from the circulation to prevent relapse in NMOSD. This approval is based on the data of global clinical study conducted by Viela Bio in patients with NMOSD including Japan. In the U.S., it was approved for the indication of NMOSD on June 11, 2020 under the name of UPLIZNA.

UPLIZNA is a drug for the treatment of NMOSD with a new mechanism, and the convenience of a dosing interval of once every six months should provide a new treatment option for NMOSD patients in the relapse prevention period. In addition, for myasthenia gravis and IgG4-related disease as indications following NMOSD, global phase 3 clinical studies including Japan are currently underway and will be conducted in collaboration with Horizon Therapeutics.

MTPC will continue to actively pursue R&D in pharmaceuticals that address unmet medical needs.

About Horizon Therapeutics plc

Horizon is focused on the discovery, development and commercialization of medicines that address critical needs for people impacted by rare, autoimmune and severe inflammatory diseases. Our pipeline is purposeful: we apply scientific expertise and courage to bring clinically meaningful therapies to patients. We believe science and compassion must work together to transform lives. For more information on how we go to incredible lengths to impact lives, please visit www.horizontherapeutics.com.

About Neuromyelitis Optica Spectrum Disorder (NMOSD)

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 population¹. 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 failure². The disease is primarily associated with anti-aquaporin 4 (AQP4) antibodies, which are detected in approximately 73%-90% of patients with NMOSD³.

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

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

³ Chang VTW, Chang HM. Review: Recent advances in the understanding of the pathophysiology of neuromyelitis optica spectrum disorder. NAN. 2020; 46:199-218.

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