

News Release

August 5, 2021

Inebilizumab has been approved in South Korea for Neuromyelitis Optica Spectrum Disorder

Mitsubishi Tanabe Pharma Corporation (MTPC) (Head Office: Osaka; President & Representative Director, CEO: Hiroaki Ueno), announced today that Mitsubishi Tanabe Pharma Korea (MTPK) (Head Office: Hwaseong, Gyeonggi-do, South Korea; President & Representative Director, CEO: Osamu Yomogida), MTPC's subsidiary in South Korea obtained the regulatory approval of UPLIZNA[®] injection (generic name: inebilizumab (genetically modified), Japan names: UPLIZNA[®] for I.V. Infusion 100mg) for the treatment of neuromyelitis optica spectrum disorder (NMOSD) on August 5, 2021.

UPLIZNA is a drug for the treatment of NMOSD with a new mechanism of which MTPC obtained license from Horizon Therapeutics plc (Horizon). Horizon received approval in the U.S. in June 2020. In Japan, MTPC received approval in March 2021 and has been marketing since June 2021.

It has been reported that the prevalence of NMOSD in South Korea is relatively high among Asian countries. In recent years, the number of patients has been increasing as diagnostic techniques have improved and there is a growing interest in diseases¹. Because of the convenience of a dosing interval of once every six months, UPLIZNA enables treatment tailored to the lifestyle of patients, and it can be provided as a new treatment option for NMOSD patients in the relapse prevention period.

Since its establishment in 1989 by MTPC, MTPK has been conducting business activities in South Korea for more than 30 years. In South Korea, MTPK are focusing on the central nervous system and have marketed Radicut, a drug for the treatment of amyotrophic lateral sclerosis since 2016. In 2020, MTPK filed an application for approval of Valbenazine (MT-5199) for the treatment of tardive dyskinesia. Through further expansion of the product lineup with the approval of UPLIZNA, MTPK will strengthen our business base in the central nervous system area.

By bringing treatment options to patients fighting against NMOSD, MTPC will strive to improving the quality of life of patients.

¹ Kim JE, Park SH, Han K, Kim HJ, Shin DW, Kim SM: Prevalence and incidence of neuromyelitis optica spectrum disorder and multiple sclerosis in Korea. *Mult Scler.* 2020; 26(14):1837-1844.

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About inebilizumab

Inebilizumab is a humanized anti-CD19 monoclonal antibody of which MTPC obtained license Horizon Therapeutics plc (formerly Viela Bio, Inc.). It 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.

About Neuromyelitis Optica Spectrum Disorder (NMOSD)

NMOSD is a rare, severe, relapsing, autoimmune disease of the central nervous system that can be fatal. 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.

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.

About Mitsubishi Tanabe Pharma Korea Co., Ltd.

Mitsubishi Tanabe Pharma Korea Co., Ltd. (MTPK) is a South Korean subsidiary established in April 1989 with a 100% investment by MTPC. MTPK is one of the few foreign-affiliated pharmaceutical companies operating in South Korea with development, manufacturing and sales functions and is rooted in South Korea.

A member of Mitsubishi Chemical Holdings Group.

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