



June 1, 2021

**Launch of UPLIZNA<sup>®</sup> for I.V. Infusion 100mg  
as a new option 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 MTPC launched UPLIZNA<sup>®</sup> for I.V. Infusion 100mg (generic name: inebilizumab (genetically modified), (UPLIZNA)) for the prevention of relapses of neuromyelitis optica spectrum disorder (including neuromyelitis optica) on June 1, 2021 following its NHI price listing on May 19, 2021. UPLIZNA is a humanized anti-CD19 monoclonal antibody and received manufacturing and marketing approval on March 23, 2021.

Neuromyelitis Optica Spectrum Disorder (NMOSD) is an autoimmune disease of the central nervous system characterized by severe optic neuritis and transverse myelitis, and 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. In global clinical study including Japan in patients with NMOSD, the primary endpoint of relapse suppression effect was confirmed by administration of UPLIZNA. 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 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. 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 plc.

MTPC will continue to actively pursue R&D in pharmaceuticals that address unmet medical needs to provide "Creating hope for all facing illness."

**Mitsubishi Tanabe Pharma Corporation**  
**Communication Crossroads Department**

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Product Name	UPLIZNA <sup>®</sup> for I.V. Infusion 100mg
JAN	Inebilizumab (genetically modified)
Indication	Prevention of relapses of NMOSD (including NMO)
Dosage	The usual adult dosage is 300 mg, and infusion at weeks 0 and 2, followed by an intravenous infusion 6 months after the first dose, and then every 6 months thereafter.
Packaging	100 mg 10 ml (vial) x 3
NHI price	3,495,304 yen / 100 mg 10 ml (vial)
Approval (Japan)	March 23,2021
NHI price listing	May 19,2021
Release (Japan)	June 1,2021
Manufacturer	Mitsubishi Tanabe Pharma Corporation.

**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](http://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 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>. The disease is primarily associated with anti-aquaporin 4 (AQP4) antibodies, which are detected in approximately 73%-90% of patients with NMOSD<sup>3</sup>.

<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>

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