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Chugai's Enspryng becomes first approved medicine for NMOSD in Taiwan

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Subcutaneous injection for the treatment of Neuromyelitis Optica Spectrum Disorder (NMOSD) in both adults and adolescents

Chugai Pharmaceutical Co., Ltd. announced that Chugai Pharma Taiwan Ltd., a wholly-owned subsidiary of Chugai, obtained an import drug license from the Taiwan Food and Drug Administration (TFDA) for Chugai's Enspryng® for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult and adolescent over 12 years old patients who are anti-aquaporin-4 (AQP4) antibody positive.

"Enspryng is the first approved product to apply our proprietary recycling antibody technology and the first NMOSD treatment targeting the IL-6 receptor. Chugai will cooperate with Chugai Pharma Taiwan so that Enspryng may be available to people with NMOSD in Taiwan as soon as possible."

Chugai's President and COO, Dr. Osamu Okuda said, "Enspryng is the first approved product to apply our proprietary recycling antibody technology and the first NMOSD treatment targeting the IL-6 receptor. Chugai will cooperate with Chugai Pharma Taiwan so that Enspryng may be available to people with NMOSD in Taiwan as soon as possible."

This approval is based on the results from 2 global phase III clinical studies to show a significantly reduced risk of relapse in people with NMOSD: SAkuraSky Study (NCT02028884) and SAkuraStar Study (NCT02073279). SAkuraSky is a study to evaluate Enspryng in combination with baseline immunosuppressive treatment, and SAkuraStar is a study to evaluate Enspryng as monotherapy.

Enspryng, created by Chugai, is the pH-dependent binding humanized anti-IL-6 receptor antibody, which was the first product developed by applying our proprietary recycling antibody technology. The medicine is believed to prevent relapses by inhibiting the cytokine IL-6 which is a key driver in NMOSD. Enspryng has been approved in Canada, Japan, Switzerland, US, Taiwan, Dominican Republic, Guyana, Indonesia, Australia and Curacao. Enspryng is designated as an orphan drug in Europe. The application was accepted for review by the European Medicines Agency in 2019.

NMOSD is an autoimmune disease of the central nervous system characterized by inflammatory lesions in the optic nerves and spinal cord, and causes a continual and significant decrease in quality of life due to permanent neurological disability.