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Chugai's Enspryng Approved in Taiwan as First Approved Medicine for Neuromyelitis Optica Spectrum Disorder (NMOSD)

- Enspryng is the first approved medicine for NMOSD in Taiwan
- Subcutaneous injection for the treatment of NMOSD in both adults and adolescents
- Enspryng is the first approved medicine applying Chugai's proprietary recycling antibody technology
- Enspryng showed a significantly reduced risk of relapse in people with NMOSD in two global phase III studies

TOKYO, December 9, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced 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.

"We are very pleased that Enspryng, created by Chugai, has been approved for the treatment of NMOSD, a disease with high unmet medical needs that has no approved treatments in Taiwan," said Chugai's President and COO, Dr. Osamu Okuda. "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.

As a leading company in biopharmaceuticals, Chugai will continue to create pharmaceutical products that meet unmet medical needs through the development of innovative technologies and their application, contributing to healthcare and the health of people around the world.

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<Reference>
・SAkuraSky study
Results from Phase III SAkuraSky Study for Chugai's Enspryng in Neuromyelitis Optica Spectrum Disorder Published in The New England Journal of Medicine Online (November 29, 2019)
https://www.chugai-pharm.co.jp/english/news/detail/20191129110000_644.html

・SAkuraStar study
Positive Results from the Second Phase III SAkuraStar Study for Chugai's Enspryng in Neuromyelitis Optica Spectrum Disorder (NMOSD) Published in The Lancet Neurology (April 24, 2020)
https://www.chugai-pharm.co.jp/english/news/detail/20200424150001_714.html

About neuromyelitis optica spectrum disorder (NMOSD)[1]
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. Patients with NMOSD frequently experience a relapsing disease course with repeated attacks leading to accumulating neurological damage and disability. Symptoms may include visual impairment, motor disability, pain leading to decreased quality of life. In some cases, attacks of NMOSD result in death. Aquaporin-4 antibodies (AQP4-IgG), pathogenic antibodies, are detected in around 70-80% of NMOSD people. AQP4-IgG is known to target and damage a specific central nervous cell type called astrocytes, resulting in inflammatory demyelinating lesions of the optic nerve(s), spinal cord and brain [2-5]. The inflammatory cytokine IL-6 is now emerging as an important factor in NMOSD pathogenesis [6-10].

Diagnostic criteria introduced in 2006 for NMO were characterized by inflammation of the optic nerve (optic neuritis) and the spinal cord (myelitis). These were revised in 2007 with the definition of NMOSD, proposed for diseases with either optic neuritis or myelitis. In 2015, the definition of NMOSD further revised to include a broader spectrum of diseases. The diagnostic term NMOSD is now accepted [11].

Sources
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