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Chugai's Enspryng (Satralizumab) Receives Regulatory Approval from FDA for Neuromyelitis Optica Spectrum Disorder

- A treatment option with a novel mechanism of action for anti-aquaporin-4 seropositive neuromyelitis optica spectrum disorder (NMOSD) approved in the U.S.
- Enspryng, the first approved drug applying Chugai's proprietary recycling antibody technology, allows patients with NMOSD to treat at home by self-injection* through subcutaneous administration every four weeks
- The approval was granted based on the results from two global phase III studies where Enspryng showed significantly reduced risk of relapse in people with NMOSD

TOKYO, August 17, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the U.S. Food and Drug Administration (FDA) has approved the pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody, Enspryng™ (US generic name: satralizumab-mwge) (hereafter, Enspryng) created by Chugai for the treatment of adults living with anti-aquaporin-4 (AQP4) antibody positive neuromyelitis optica spectrum disorder (NMOSD). Enspryng is administered subcutaneously every four weeks**. Enspryng was granted Breakthrough Therapy Designation in December 2018 and the US Biologics License Application (BLA) was filed in August 2019 by Genentech Inc., a member of Roche Group.

This approval is based on the results from two global phase III clinical studies in patients 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 a pH-dependent binding humanized anti-IL-6 receptor antibody, which was the first product developed by applying our proprietary recycling antibody technology. The drug is believed to prevent relapse of NMOSD by inhibiting IL-6 signal signaling which is a key driver in NMOSD. Enspryng has been approved in Canada, Japan and Switzerland. Enspryng is designated as an orphan drug in Europe. The application was accepted for review by the European Medicines Agency in 2019.

*Self-administration is not included in Japanese package insert
**Subcutaneous administration at 2-week intervals up to the fourth week of treatment and at 4-week intervals thereafter

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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)
NMOSD is an autoimmune disease of the central nervous system characterized by inflammatory lesions in the optic nerves and spinal cord, and cause 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 at least two-thirds 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 [1-4]. The inflammatory cytokine IL-6 is now emerging as an important factor in NMOSD pathogenesis [5-9].

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 widely used [10].

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