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Chugai's Enspryng (Satralizumab) Approved by European Commission as First At-home Subcutaneous Treatment for Neuromyelitis Optica Spectrum Disorder (NMOSD)

- Enspryng is a new treatment approved for both adults and adolescents with AQP4-IgG seropositive NMOSD in the EU. It is the first treatment approved in the EU for adolescents from 12 years of age with NMOSD.
- Enspryng is the first approved medicine applying Chugai's proprietary recycling antibody technology. It can be self-administered* subcutaneously at home every four weeks**
- Enspryng significantly reduced risk of relapse in people with AQP4-IgG seropositive NMOSD in two global phase III studies.
- The medicine has been approved in 54 countries including Japan, the United States and the EU.

TOKYO, June 28, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced today that Roche has been granted Marketing Authorization from the European Commission for the pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Enspryng® (satralizumab), created by Chugai, as the first subcutaneous treatment option for adults and adolescents from 12 years of age living with anti-aquaporin-4 antibody (AQP4-IgG) seropositive neuromyelitis optica spectrum disorder (NMOSD), as a monotherapy or in combination with immunosuppressive therapy (IST). Enspryng is the first treatment approved in the EU for adolescents from 12 years of age with NMOSD.

"We are very pleased that Enspryng is now approved in the EU as the first subcutaneous treatment for people with AQP4-IgG seropositive NMOSD, with the option to be treated at home," said Chugai's President and CEO, Dr. Osamu Okuda. "Enspryng is the first approved therapeutic antibody for which our proprietary recycling antibody technology was applied. We are confident that Enspryng will meaningfully contribute to improving the treatment of people with NMOSD, by fitting into their day-to-day lives."

The efficacy and safety of Enspryng has been evaluated in large clinical trials representative of the real-world population of people with NMOSD, including those who have only experienced a single NMOSD attack and adolescents. The approval by the European Commission is based on the results from two global phase III

clinical studies in people with NMOSD: SAkuraSky Study (NCT02028884) and SAkuraStar Study (NCT02073279). SAkuraSky evaluated Enspryng in combination with baseline immunosuppressive treatment, and SAkuraStar assessed monotherapy.

Enspryng is designed to prevent NMOSD relapses by inhibiting IL-6 signal signaling, which is a key driver in NMOSD. Enspryng is currently approved in 54 countries including Japan, the United States and EU countries.

The impact on the consolidated financials for the fiscal year ending December 2021 of Chugai is expected to be negligible.

*Self-administration is not covered in Japan at this time
**Subcutaneous administration at 2-week intervals up to the fourth week of treatment and at 4-week intervals thereafter

<Reference>
New Data of Chugai's Enspryng (Satralizumab) on Risk and Severity of Relapse in Neuromyelitis Optica Spectrum Disorder (NMOSD) (September 10, 2020)
https://www.chugai-pharm.co.jp/english/news/detail/20200910150000_765.html

・SAkuraSky study
Results from Phase III SAkuraSky Study for Chugai's Satralizumab 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 Satralizumab 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].

Sources

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