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New Four-year Data Show Sustained Relapse Reduction by Chugai's Enspryng in People with Neuromyelitis Optica Spectrum Disorder (NMOSD)

- New data demonstrate Enspryng's robust and sustained longer-term efficacy in preventing relapses in people with NMOSD
- More than 70% of people treated with Enspryng remained relapse-free after four years in the SAkuraStar (73%) and SAkuraSky (71%) open-label extension studies, reinforcing the long-term safety profile

TOKYO, October 14, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced new longer-term efficacy and safety data for Enspryng® [generic name: satralizumab (genetical recombination)], a pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody created by Chugai. The data show Enspryng has a favourable benefit:risk profile and is effective in reducing relapses over four years of treatment in people with anti-aquaporin-4 antibody (AQP4-IgG) seropositive neuromyelitis optica spectrum disorder (NMOSD), a rare debilitating disease that affects the central nervous system. Efficacy and safety results from the open-label extension (OLE) periods of the SAkuraStar and SAkuraSky studies, in addition to the design of SAkuraBONSAI, a new study in people with AQP4-IgG seropositive NMOSD who are treatment naïve, or where prior rituximab (or biosimilar) treatment has failed, will be presented at the 37th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS).

"The data show that the efficacy and safety of Enspryng, which inhibits IL-6 signaling, are sustained over time. NMOSD is a lifelong disease where prevention of relapse is crucial, and its treatment often lasts several years. We believe that these data provide important evidence to help patients and healthcare professionals continue treatment with Enspryng with confidence," said Dr. Osamu Okuda, Chugai's President and CEO. "In Japan, Enspryng became available for self-administration in September 2021, which allows patients to take treatment at home. We will continue providing information on the appropriate use of this drug so that Enspryng may further contribute to the treatment of NMOSD."

The pivotal phase III SAkuraStar and SAkuraSky four year overall treatment data found that 73% and 71% of people with AQP4-IgG seropositive NMOSD treated with Enspryng remained relapse-free after 192 weeks (3.7 years), respectively, and 90% and 91% remained free from severe relapse*. These results demonstrate that the robust efficacy observed in the studies' double-blind periods is sustained longer-term for Enspryng as both a monotherapy and in combination with immunosuppressive therapy.

*Relapse associated with low likelihood of recovery resulting in permanent disability

The data also reinforce that the safety profile of Enspryng in the overall Enspryng treatment period of up to seven years, is comparable to the double-blind treatment periods in both SAkuraStar and SAkuraSky

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studies. Rates of adverse events and serious adverse events during the overall treatment periods were consistent with Enspryng and placebo in the double-blind treatment periods. No new safety signals were observed.

Roche is also launching SAkuraBONSAI, a multicentre, Phase 3b, international study, to further evaluate disease activity and progression using comprehensive imaging, biomarker and clinical assessments in NMOSD populations where further research is warranted. People with AQP4-IgG seropositive NMOSD, who are treatment-naïve or where prior rituximab (or biosimilar) treatment has failed, will be administered Enspryng monotherapy for two years and evaluated using clinical measures such as magnetic resonance imaging, optical coherence tomography and biomarkers of blood and cerebrospinal fluid.

About Enspryng

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 designed to prevent relapse of neuromyelitis optica spectrum disorder (NMOSD) by inhibiting the cytokine IL-6 which is a key driver in NMOSD. In two global phase III clinical studies in Neuromyelitis Optica and NMOSD, the primary endpoint was achieved with satralizumab either as combination therapy with baseline immunosuppressive treatment (SAkuraSky; NCT02028884) or as monotherapy (SAkuraStar; NCT02073279). These studies represent one of the largest clinical trial programs undertaken for this rare disease. Enspryng has been approved in 58 countries including Japan, the U.S. the EU and Canada.

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. The disease can lead to 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 can result in death. Aquaporin-4 antibodies (AQP4-IgG), pathogenic antibodies, are detected in the blood of around 70-80% of people with NMOSD. 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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