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Chugai Presents Results from Second Positive Global Phase III Clinical Study of Satralizumab

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Pivotal Phase III SAkuraStar study shows 55% reduction in the risk of relapse for satralizumab monotherapy versus placebo presented at ECTRIMS Congress 2019

Chugai Pharmaceutical Co., Ltd. (TOKYO:4519) announced that the results from SAkuraStar Study were presented at the Congress of European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) 2019 (from September 11 to 13). SAkuraStar study is a phase III multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of an investigational anti-IL-6 receptor humanized recycling antibody satralizumab (development code: SA237) as monotherapy for the treatment of neuromyelitis optica spectrum disorder (NMOSD).

In SAkuraStar study, satralizumab significantly reduced the risk of relapse by 55% (hazard ratio=0.45 [95% confidence interval: 0.23-0.89], p=0.0184 [stratified log-rank test]) in the overall population, representative of NMOSD patients (including aquaporin-4 antibodies [AQP4-IgG] seropositive and seronegative patients). Satralizumab has shown a favorable safety profile during the study.

“Satralizumab is the first investigational medicine for the treatment of NMOSD that has demonstrated benefits both as a monotherapy and add-on therapy to baseline treatment in two separate trials, suggesting that IL-6 inhibition could be a novel therapeutic approach for NMOSD, and satralizumab may contribute to a broad range of patients,” said Dr. Yasushi Ito, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit. “NMOSD is a disease in which relapse may lead to accumulation of disabilities, and can be life-threatening. We will collaborate with Roche to file global regulatory applications this year so that we can bring satralizumab as a potential new treatment to patients as soon as possible.”

SAkuraStar Study (NCT02073279)

Summary:

A phase III multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of satralizumab administered to patients with NMOSD

[Primary Endpoint]

Time to first protocol-defined relapse adjudicated by an independent review committee in the double-blind period
[Main Secondary Endpoints]
Visual Analogue Scale (VAS) score for pain
Functional Assessment of Chronic Illness Therapy (FACIT) Fatigue score

Study design:

- 95 male and female patients aged from 20 to 70 years were randomized.
- Patients were randomized to satralizumab or placebo in a 2:1 ratio. Satralizumab (120 mg) or placebo was subcutaneously administered at Week 0, 2, and 4. The subsequent treatment was continued at 4-week intervals.
- The double-blind treatment period ended when the total number of protocol-defined relapse (PDR) had reached 44 or at 1.5 years after the enrollment of the last patient, whichever occurred first. After experiencing a PDR or completion of the study, patients in both groups were offered treatment with satralizumab in an open-label extension period.
- Patients with AQP4-IgG seropositive or seronegative neuromyelitis optica (NMO)* and those with AQP4-IgG seropositive NMOSD were enrolled.
  *NMO defined in 2006

Main results:

- Satralizumab significantly reduced the risk of relapse by 55% (hazard ratio=0.45 [95% confidence interval: 0.23-0.89], p=0.0184 [stratified log-rank test]) in the overall population, representative of NMOSD patients (including AQP4-IgG seropositive and seronegative patients), achieving the primary endpoint of time to first protocol-defined relapse in the double-blind period.
- In a prespecified subgroup analysis for time to relapse, hazard ratio of satralizumab to placebo in AQP4-IgG seropositive patients was 0.26 (N=64, 95% confidence interval: 0.11-0.63).
- Satralizumab has shown a favorable safety profile during the study. The proportion of serious adverse events, including serious infections, was similar in patients treated with satralizumab or placebo.