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Chugai's Satralizumab Meets Primary Endpoint in Phase III Monotherapy Study in NMOSD

- Satralizumab monotherapy significantly reduced risk of relapse -

TOKYO, December 19, 2018 – Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that a phase III monotherapy study of satralizumab (development code: SA237), SAkuraStar Study (NCT02073279) for the treatment of neuromyelitis optica spectrum disorder (NMOSD), which currently has no approved treatments, has achieved the primary endpoint. The primary endpoint was time to first protocol-defined relapse in the double-blind period. A statistically significant reduction in the risk of relapse was confirmed in patients who received satralizumab, compared to those who received placebo. Furthermore, the safety profile of satralizumab was consistent with that seen in previous studies. Further details will be presented at a future medical meeting.

"We are pleased that satralizumab showed benefits also in a monotherapy setting following the previous results as add-on to baseline treatment in patients with NMOSD," said Dr. Yasushi Ito, Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit. "We will work diligently to prepare for regulatory filing so that we can offer a new treatment option to patients with NMOSD as soon as possible."

SAkuraStar Study

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:

- About 90 male and female patients aged from 18 to 74 years were randomized.
- Patients were randomized to either of the following two treatment groups 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 period ended when the total number of protocol-defined relapse had reached 44 or at 1.5 years after the enrollment of the last patient, whichever occurred first.

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After completion of the double-blind period, patients in both groups were able to continue treatment with satralizumab in an open-label extension period.

- Patients with neuromyelitis optica (NMO, as defined by the diagnostic criteria in 2006) and those with NMOSD (as defined by the diagnostic criteria in 2007) with anti-aquaporin-4 (AQP4) antibodies were enrolled.

[Reference]
Press release issued on October 15, 2018
Chugai Presents Results from Phase III Study of Satralizumab in NMOSD at ECTRIMS 2018
https://www.chugai-pharm.co.jp/english/news/detail/20181015120001_561.html

About Chugai

Chugai Pharmaceutical is one of Japan's leading research-based pharmaceutical companies with strengths in biotechnology products. Chugai, based in Tokyo, specializes in prescription pharmaceuticals and is listed on the 1st section of the Tokyo Stock Exchange. As an important member of the Roche Group, Chugai is actively involved in R&D activities in Japan and abroad. Specifically, Chugai is working to develop innovative products which may satisfy the unmet medical needs, mainly focusing on the oncology area.
In Japan, Chugai's research facilities in Gotemba and Kamakura are collaborating to develop new pharmaceuticals and laboratories in Ukima are conducting research for technology development for industrial production. Overseas, Chugai Pharmabody Research based in Singapore is engaged in research focusing on the generation of novel antibody drugs by utilizing Chugai's proprietary innovative antibody engineering technologies. Chugai Pharma USA and Chugai Pharma Europe are engaged in clinical development activities in the United States and Europe.
The consolidated revenue in 2017 of Chugai totalled 534.2 billion yen and the operating income was 103.2 billion yen (IFRS Core basis).
Additional information is available on the internet at https://www.chugai-pharm.co.jp/english.

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