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Chugai Pharma's study on satralizumab published in The New England Journal of Medicine

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The New England Journal of Medicine published the results of the Sino-foreign pharmaceutical satralizumab in the treatment of panoptic neuromyelitis phase III SAkuraSky



Chugai Pharmaceutical has announced that the "New England Journal of Medicine" (NEJM) online edition November 27 Results of the global phase III SAkuraSky clinical study (NCT02028884) of satralizumab (development code SA237) were published. satralizumab is an anti-IL6 receptor humanized recovered antibody that is being developed for the treatment of panoptic neuromyelitis (NMOSD). This phase III study explores the efficacy and safety of satralizumab as a baseline therapeutic in NMOSD patients.

Dr. Yasushi Ito, Executive Vice President of Sinopharm, Co-Head of Project and Lifecycle Management Department, said, "Relapse of NMOSD can lead to cumulative disability and can be life-threatening. The above information further reinforces the importance of IL-6 signal suppression in NMOSD treatment. "The SAkuraSky study is the first clinical study to demonstrate the efficacy and safety of a drug in a trial to treat NMOSD, with or without AQP4-IgG expression in patients."

The SAkuraSky study showed that in the general population representing NMOSD patients (including anti-AQP4-IgG antibody seropositive and negative patients), protocol-defined relapse (PDR) occurred, and only 8 of the 41 patients in the satralizumab combined with the baseline immunosuppressive group (20%), compared with 18 (43%) of the 42 patients in the placebo plus baseline treatment group (HR = 0.38, 95% CI: 0.16-0.88; p = 0.02 [hierarchical log-rank test]).Importantly, the proportion of relapse-free at weeks 48, 96, and 144 was 89%, 78%, and 74% in the satralizumab group, compared to 66%, 59%, and 49% in the placebo group. The proportion of severe adverse events was similar in the satralizumab and placebo groups.

Overview of the SAkuraSky Study (NCT02028884)
: A
phase III multicenter, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of satralizumab

added to baseline therapy in patients with NMOSD

[Primary endpoint]
Double-blind period Determined by the independent review committee to the protocol-defined first relapse time

Research design:

- Eighty-three male and female patients aged 13 to 73 were enrolled.
- Patients were randomized to receive satralizumab or placebo in a 1: 1 ratio. Based on baseline treatments (azathioprine, mycophenolate mofetil, and / or corticosteroids *), satralizumab (120 mg) or placebo was administered subcutaneously at weeks 0, 2, and 4. Follow-up treatments are performed every 4 weeks.
- The total number of PDRs reached 26, and the double-blind treatment period ended. After the onset of PDR or completion of the study, both groups of patients continued to receive the open extension of satralizumab.
- AQP4-IgG seropositive or negative optic neuromyelitis (NMO) ** patients and AQP4-IgG seropositive NMOSD were enrolled.
  * Mycophenolate mofetil's approved indications in Japan are for refractory rejection after kidney transplantation (if the patient cannot be treated with existing drugs due to lack of efficacy, adverse reactions, or other reasons, and has been diagnosed with refractory rejection), inhibit organ transplant (Kidney, heart, liver, or pancreas transplantation). Rejection, lupus erythematosus nephritis. For other drugs, please refer to the latest version of the package insert for each drug.
  ** NMO is defined in 2006

Main results:

- Preset primary analysis showed that only 8 of 41 patients in the satralizumab combined with baseline immunosuppressive group who had a protocol-defined relapse (PDR) in the general population representing NMOSD patients (including anti-AQP4-IgG antibody seropositive and negative patients) Cases (20%), compared with 18 (43%) of the 42 patients in the placebo combination group (HR = 0.38, 95% CI: 0.16-0.88; p = 0.02 [hierarchical log-rank test]) . Post hoc analysis using limit data for multiple interpolations showed that the same stable results were obtained for satralizumab.
- Recurrence-free rates at weeks 48, 96, and 144 were 89%, 78%, and 74% in the satralizumab group, compared to 66%, 59%, and 49% in the placebo group.
- Pre-set analysis showed that in the AQP4-IgG seropositive subgroup, PDR occurred in 3 of the 27 patients in the satralizumab group (11%), compared with 12 of the 28 patients in the placebo group (43%) (HR = 0.21, 95% CI: 0.06-0.75). In the AQP4-IgG sero-negative subgroup, 5 of the 14 patients in the satralizumab group (36%) compared with 6 of the 14 patients in the placebo group (43%) (HR = 0.66, 95%). CI: 0.20-2.24).
- The proportion of severe adverse events was similar in the satralizumab and placebo groups. The rate of infection (including severe infections) was lower in the satralizumab group than in the placebo group. The most common adverse events in the satralizumab group were upper respiratory infections, nasopharyngitis (cold), and headache.