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Results of Phase III Study of Enspryng in Patients with Generalized Myasthenia Gravis

- Statistically significant data was observed in the primary endpoint of the phase III LUMINESCE study, however the results did not reach our expectations on the degree of clinical benefit
- Enspryng safety profile in generalized myasthenia gravis (gMG) is consistent with that in neuromyelitis optica spectrum disorder (NMOSD)
- Detailed results will be presented at the American Academy of Neurology (AAN) 2024 Annual Meeting

TOKYO, March 21, 2024 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) today announced results from the Phase III LUMINESCE study of Enspryng® (generic name: satralizumab (genetical recombination)), created by Chugai, as an investigational treatment for generalized myasthenia gravis (gMG). Statistically significant data was observed in its primary endpoint, however the results did not reach our expectations on the degree of clinical benefit. Enspryng was well tolerated in gMG, with a safety profile consistent with Enspryng in neuromyelitis optica spectrum disorder (NMOSD) which is the medicine's first indication. Detailed results will be presented as an oral Emerging Science abstract at the American Academy of Neurology (AAN) 2024 Annual Meeting on 15 April in Denver, Colorado.

The results of this study in gMG do not impact Enspryng in NMOSD, in which the medicine is already approved. Chugai, in collaboration with Roche, is committed to developing Enspryng in additional neurological autoimmune and inflammatory diseases that may benefit from the inhibition of interleukin-6 (IL-6) signaling, including autoimmune encephalitis (AIE), myelin oligodendrocyte glycoprotein-associated disorder (MOGAD) and thyroid eye disease (TED).

About Enspryng

Enspryng, created by Chugai, is a pH-dependent binding humanized anti-IL-6 monoclonal receptor antibody that targets interleukin-6 (IL-6). It was the first product developed by applying our proprietary Recycling Antibody® technology, which, compared to conventional technology, allows for sustained IL-6 inhibition, and subcutaneous administration every four weeks.

Enspryng is the first and only IL-6 inhibitor treatment currently approved in 89 countries for aquaporin-4 immunoglobulin (AQP4-IgG) seropositive neuromyelitis optica spectrum disorder (NMOSD) with additional applications under health authority review in other countries.

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About LUMINESCE study

LUMINESCE is a Phase III, global, multicentre, randomised trial evaluating the efficacy and safety of Enspryng compared with placebo in 188 adults and adolescents 12 years of age and older with generalized myasthenia gravis (gMG)*. All patients received ongoing standard-of-care therapy throughout the trial (acetylcholinesterase inhibitors, oral corticosteroids, azathioprine, mycophenolate mofetil, cyclosporine or tacrolimus).

*patients positive for antibodies targeting either acetylcholine receptor (AChR), muscle-specific tyrosine kinase (MuSK) or low-density lipoprotein receptor-related protein 4 (LRP4)

The primary endpoint was the mean change from baseline in total Myasthenia Gravis Activities of Daily Living (MG-ADL) score at 24 weeks in the anti-AChR-seropositive (AChR+) population. The MG-ADL measured symptoms and their impact to daily life, including talking, chewing, swallowing, breathing, brushing teeth or hair, rising from a chair, double vision and eyelid droop.

Secondary endpoints included the mean 24-week change from baseline in MG-ADL score and other endpoints in the overall study population (AChR+, MuSK+ or LRP4+): Quantitative Myasthenia Gravis (QMG) score, Myasthenia Gravis Quality of Life 15 Scale (MG-QOL 15r) score, Quality of Life in Neurological Disorders (Neuro-QoL) Fatigue Subscale score, total Myasthenia Gravis Composite (MGC) score, as well as the proportion of patients who experienced clinically meaningful improvement of MG-ADL, QMG or MGC scores or who achieved minimal disease manifestation (total MG-ADL score of 0 or 1).

About generalized myasthenia gravis[1]

Generalised myasthenia gravis (gMG) is a rare, chronic, autoimmune disease that breaks down the communication between nerves and muscles, leading to muscle weakness. Muscle weakness occurs through repeated activity, and symptoms fluctuate throughout the day, including improvement with rest and worsening in the evening, as well as day to day.[2] People with gMG typically experience difficulties with facial expression, chewing, speaking, swallowing, weakness in the arms, legs and neck, and shortness of breath. People with gMG may also experience ocular symptoms, such as drooping eyelids and double vision. The symptoms, including immense fatigue, may have a large impact on a person's daily life and how they are able to engage in normal, everyday activities (such as brushing teeth and eating). About 15-20% of people with gMG develop myasthenic crisis, which is a life-threatening inability to breathe and swallow.

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Source:

1. Neurological Disorders. Myasthenia gravis fact sheet. 2020. Available from: https://www.ninds.nih.gov/sites/default/files/migrate-documents/myasthenia_gravis_e_march_2020_508c.pdf. Accessed March 2024
2. Japanese Society of Neurology. Guidelines for the treatment of myasthenia gravis and Lambert-Eaton myasthenic syndrome 2022. Available from: https://www.neurology-jp.org/. Accessed March 2024 (Japanese only)

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