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Chugai Receives Forerunner Designation for Enspryng in Myelin Oligodendrocyte Glycoprotein Antibody-associated Disease (MOGAD) and Autoimmune Encephalitis (AIE)

- MOGAD and AIE are autoimmune diseases in the central nervous system with no approved therapies and high unmet medical needs
- A global phase III study of each disease is ongoing with Enspryng

TOKYO, March 24, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that its pH-dependent binding humanized anti-IL-6 receptor monoclonal antibody Enspryng® [generic name: satralizumab (genetical recombination)], created by Chugai, received forerunner designation for the expected indication for the treatment of myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD) and autoimmune encephalitis (AIE) from the Ministry of Health, Labour and Welfare (MHLW).

"We are very pleased that the MHLW granted Enspryng as an innovative drug candidate for treating MOGAD and AIE with no approved therapies," said Dr. Osamu Okuda, Chugai's President and CEO. "We intend to proceed with the ongoing global clinical phase III study of each disease in cooperation with Roche to deliver Enspryng to patients waiting for new therapies as soon as possible."

About forerunner designation

Forerunner designation aims at shortening the pre-market review period for innovative medical products that satisfy certain criteria by designating such products during the early stages of development and providing prioritized consultation services and substantial pre-application consultation. Under this system, the review period is intended to be less than six months.

About Enspryng

Enspryng, created by Chugai, a member of the Roche group, is a pH-dependent binding humanized anti-IL-6 receptor antibody, which was the first product developed by applying our proprietary recycling antibody® technology. Enspryng is approved for the treatment of neuromyelitis optica spectrum disorder (NMOSD) in more than 75 countries, including Japan, the United States, and Europe. A global clinical phase III study in generalized myasthenia gravis, myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)[1] and autoimmune encephalitis (AIE)[2] is ongoing.

About myelin oligodendrocyte glycoprotein antibody-associated disease (MOGAD)

MOGAD is an autoimmune disease involving demyelination by which a pathogenic autoantibody, an anti-MOG antibody, binds to MOG, which is expressed on the surface of the myelin sheath in the central nervous system. Symptoms include optic neuritis, myelitis, and encephalitis (visual impairment, loss of

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sensation, motor dysfunction, dysuria, etc.).[3,4] Currently, no approved therapies exist for the prevention of relapse in MOGAD, and in about 80% of adult patients, the disease is chronic, characterized by a relapsing course on available off-label therapies. Therefore, high unmet medical needs remain for efficacy and/or safety.[3-9] The inflammatory cytokine IL-6 may play a role in the pathogenesis of MOGAD, by promoting the production of autoantibody[10] and by inducing inflammatory effects.[11] The number of patients in Japan is estimated to be 1,700.[12]

About autoimmune encephalitis (AIE)

AIE is an autoimmune disease caused by direct damage to nerve cells in the central nervous system (CNS) by immune cells or dysfunction due to pathogenic autoantibodies,[13] including anti-NMDA receptor encephalitis and anti-LGI1 antibody encephalitis.[14] Symptoms include consciousness disturbance, memory disorder, and convulsion-like seizures. In some cases, attacks of AIE result in death.[14] There are no approved therapies for AIE. Since currently used off-label therapies do not show sufficient efficacy and safety, unmet medical needs remain high.[13,14] The inflammatory cytokine IL-6 may play a role in the pathogenesis of AIE by promoting the production of pathogenic autoantibody[10] and by inducing inflammatory effects.[11] The annual number of patients in Japan is estimated to be approximately 1,000.[15]

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