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Chugai Files for Additional Indication of Actemra for Cytokine Release Syndrome Induced by Cancer Treatment in Japan

TOKYO, February 28, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it filed regulatory applications with the Ministry of Health, Labour and Welfare for the humanized anti-human IL-6 receptor monoclonal antibody, "Actemra® Intravenous Infusion 80 mg, 200 mg, and 400 mg" [generic name: tocilizumab (genetical recombination)] for the treatment of cytokine release syndrome induced by cancer treatment. This application is based on the clinical study results of an antineoplastic agent.

"We are very pleased to file for regulatory application of Actemra for the additional indication of cytokine release syndrome induced by cancer treatment in Japan," said Chugai's President and CEO, Dr. Osamu Okuda. "Cytokine release syndrome, a common adverse reaction in CAR-T cell therapy and some antibody drugs, can be life-threatening in severe cases. We are closely working with the Japanese health authority to ensure that proper treatment is provided to patients on cancer therapies other than CAR-T cell therapy."

About Actemra

Actemra is the first therapeutic antibody created in Japan by Chugai. It is designed to block the activity of IL-6, a type of inflammatory cytokine. First launched in June 2005, the intravenous injection is approved for seven indications in Japan: Castleman's disease, rheumatoid arthritis, systemic juvenile idiopathic arthritis, polyarticular juvenile idiopathic arthritis, cytokine release syndrome induced by tumor-specific T cell infusion therapy, adult Still's disease, and SARS-CoV-2 pneumonia. In addition, Actemra subcutaneous injection is approved for three indications in Japan: rheumatoid arthritis, Takayasu arteritis, and giant cell arteritis. Actemra has obtained regulatory approval in more than 110 countries worldwide.

About Cytokine Release Syndrome

Cytokine release syndrome (CRS) is induced by the release of high levels of cytokines associated with excessive immune response and results in an extreme elevation of cytokine concentration in the blood.[1] CRS is an adverse reaction common in cancer treatment, including CAR-T cell therapy and some antibody drugs, and many patients show mild to moderate influenza-like symptoms (pyrexia, nausea and chills, myalgia, etc.). However, severe hypotension, tachycardia, dyspnea, and others may be induced in some patients, and the symptoms may progress rapidly and may lead to death.

Reference

1. Lee DW, et al. Current concepts in the diagnosis and management of cytokine release syndrome. Blood. 2014 Jul 10; 124(2): 188-95

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CHUGAI PHARMACEUTICAL CO., LTD. Corporate Communications Dept.
1-1, Nihonbashi-Muromachi 2-chome, Chuo-ku Tokyo, 103-8324 Japan
Media Relations Group TEL:+81-(0)3-3273-0881 E-mail:pr@chugai-pharm.co.jp
Investor Relations Group TEL:+81-(0)3-3273-0554 E-mail:ir@chugai-pharm.co.jp