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Humanized Anti-Human IL-6 Receptor Monoclonal Antibody "ACTEMRA®," Application for Approval of Additional Indication of Cytokine Release Syndrome Induced by Treatment with CAR-T Cell Therapy

TOKYO, May 29, 2018 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it filed an application with the Japanese Ministry of Health, Labour and Welfare (MHLW) for the approval of an additional indication of cytokine release syndrome (CRS) induced by treatment with chimeric antigen receptor (CAR) -T cell therapy 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)] on May 28.

The application is based on the results of phase II global studies, etc. conducted by Novartis to evaluate the efficacy and safety of CAR-T cell therapy.

CRS is induced by the release of a large amount of cytokine in association with excessive immune response, and results in an extreme elevation of cytokine concentration in the blood.* CRS is an adverse reaction relatively common in CAR-T cell therapy, 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.

In the initial treatment of CRS, supportive care for individual signs and symptoms, or inhibition of hyper inflammatory reactions by intravenous corticosteroids and anti-histamine agents is conducted. In severe cases, however, treatment with anti-cytokine therapy is conducted to inhibit excessive elevation of cytokine concentration in the blood, which is the cause of the condition.

Chugai will work to provide ACTEMRA as a new treatment option for CRS induced by treatment with CAR-T cell therapy as soon as possible.

* 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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