



Humanized Anti-Human IL-6 Receptor Monoclonal Antibody “ACTEMRA®,” Application for Approval of Additional Indication of Adult Onset Still's Disease

TOKYO, May 24, 2018 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today that it filed an application with the Japanese Ministry of Health, Labour and Welfare (MHLW) for the approval of an additional indication of adult onset Still's disease 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)].

The application is based on the data from “clinical trial of tocilizumab for adult onset Still's disease,” an investigator-initiated study. The study was a multicenter study conducted at eight sites, led by Keio University Hospital which was designated in July 2011 as a hub of pharmaceutical/incurable immune disease areas, as part of the “Project for Early/Exploratory Clinical Trial Centers” by the government. The study was a placebo-controlled, randomized, double-blinded study to validate efficacy and safety of ACTEMRA in patients with inadequate responses to treatment with corticosteroids.

Adult onset Still's disease is an autoimmune disease and specified as an intractable disease by the government. The disease typically develops at the age of 16 or older, presenting with a triad including fever of 39°C or higher, arthritis, and light pink skin rash. The male-to-female ratio of the patients is 1:1.3, occurring more often in women. The mean age at onset is 46.5 years and the disease is reportedly relatively more common in young adults. Although the cause is unknown, a large quantity of inflammatory cytokines produced by monocytes in leukocytes and macrophages is thought to elicit intense internal inflammation.

According to the survey between 2010 and 2011 conducted by the MHLW research group, the number of patients is estimated to approximately 4,800 in Japan. The standard therapy of the disease is suppression of inflammation with corticosteroids; however, no drug covered by the National Health Insurance is currently available for intractable steroid-resistant patients, which accordingly increases unmet medical needs.

Chugai will work to provide ACTEMRA as a new treatment option for patients with adult onset Still's disease as soon as possible.

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