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Chugai's Actemra Intravenous Infusion receives additional approval for Adult Still's Disease

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The first approved treatment for adult Still's disease that has not responded sufficiently to existing therapies

Chugai Pharmaceutical has announced that it has obtained regulatory approval 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]) from the Ministry of Health, Labour and Welfare (MHLW) for an additional indication of "adult Still's disease that has not responded sufficiently to existing therapies" and an additional dosing regimen for the indication.

Adult Still's disease is an autoimmune disease and specified as an intractable disease by the government. The disease typically presents with a triad including fever of 39°C or higher, arthritis, and light pink skin rash.

Dr. Yasushi Ito, Chugai's Executive Vice President, Co-Head of Project & Lifecycle Management Unit said, "Corticosteroids are the current standard of care for adult Still's disease. There are high needs for new therapies for inadequate responders and relapsed patients. Actemra has been approved for the treatment of seven diseases with high unmet medical needs where some patients experience inadequate response to existing therapies or there are no established standard of care. We are very pleased that Actemra has become the first approved treatment in Japan for adult Still's disease, which enables us to deliver the drug to patients."

This approval is based on data including results from the "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. The hospital was designated as a hub of pharmaceutical/incurable immune disease areas in July 2011, as part of the "Project for Early/Exploratory Clinical Trial Centers" by the Japanese 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.