

Innovation all for the patients


 A member of the Roche group

Chugai's Actemra Intravenous Infusion Receives Additional Approval for Adult Still's Disease

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

TOKYO, May 22, 2019 -- [Chugai Pharmaceutical Co., Ltd.](#) (TOKYO: 4519) announced today 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.

“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,” said Dr. Yasushi Ito, Chugai’s Executive Vice President, Co-Head of Project & Lifecycle Management Unit. “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.

Prescribing Information *The underlined parts were newly added.

[Indications]

- The following diseases that have not responded sufficiently to existing therapies: rheumatoid arthritis (including inhibition of structural joint damage), polyarticular-course juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and adult Still's disease
- Improvement of symptoms and laboratory findings associated with Castleman's disease (high C-reactive protein, high fibrinogen, elevated erythrocyte sedimentation rate, low hemoglobin, low albumin, and general malaise), excluding those for whom lymphadenectomy is indicated.
- Cytokine release syndrome induced by tumor-specific T cell infusion therapy

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

[Dosage and Administration]

- Rheumatoid arthritis and polyarticular-course juvenile idiopathic arthritis
The recommended dose of tocilizumab (genetical recombination) is 8 mg/kg as a single intravenous injection administered at 4-week intervals.
- Systemic juvenile idiopathic arthritis, adult Still's disease and Castleman's disease
The recommended dose of tocilizumab (genetical recombination) is 8 mg/kg as a single intravenous injection administered at 2-week intervals. The dosing interval can be shortened to a minimum of 1 week depending on patients' disease symptoms.
- Cytokine release syndrome
The recommended dose of tocilizumab (genetical recombination) is 8 mg/kg in patients weighing at least 30 kg and 12 mg/kg in patients weighing less than 30 kg, as a single intravenous injection.

About Adult Still's disease

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. 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 be 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.

*Japan Intractable Diseases Information Center. Available from: <http://www.nanbyou.or.jp/entry/132>. Accessed April 2019. (Japanese only)

Trademarks used or mentioned in this release are protected by law

###