Innovation all for the patients

CHUGAI

Roche A member of the Roche group

Chugai Obtains Approval for Additional Indication of Actemra for Cytokine Release Syndrome Induced by Cancer Therapy in Japan

- First treatment approved in Japan for cytokine release syndrome induced by cancer therapy
- Actemra is now available not only for previously approved cytokine release syndrome induced by tumor-specific T-cell infusion therapy but also for cytokine release syndrome associated with various types of cancer treatment

TOKYO, September 25, 2023 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained today, regulatory approval from 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 an additional indication of treatment of cytokine release syndrome induced by cancer therapy. Actemra was approved for the indication of cytokine release syndrome induced by tumor-specific T-cell infusion therapy in March 2019. This additional indication will make it possible to administer the drug as an anti-cytokine therapy for cytokine release syndrome (CRS) in the cancer treatment other than tumor-specific T cell infusion therapy.

"Cytokine release syndrome is one of the adverse reactions seen with cancer treatment and can be life-threatening if severe. It is significant to be able to make Actemra widely available as the first anti-cytokine therapy for cytokine release syndrome induced by any type of cancer therapy, not only for the already approved use during tumor-specific T cell infusion therapy," said Chugai's President and CEO, Dr. Osamu Okuda. "We will promote the proper use of Actemra, so that it may support the smooth procedure of cancer treatment."

The approval was based on results of a Japanese phase I/II clinical study of epcoritamab (genetical recombination) in patients with relapsed or refractory B-cell non-Hodgkin's lymphoma conducted by Genmab.

As a leading company in the field of oncology, Chugai is committed to advancing the proper use of Actemra so that it can contribute to the treatment of cytokine release syndrome induced by cancer therapy.

Approval Information *Changes are underlined

Indications:

Cytokine Release Syndrome (CRS) induced by <u>cancer therapy</u>

Dosage and administrations (No change from approved Dosage and Administration):

The recommended dose of tocilizumab (genetical recombination) is 8 mg/kg in patients weighing ≥30 kg and 12 mg/kg in patients weighing <30 kg, as a single intravenous drip infusion

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

[Reference Information]

Chugai Files for Additional Indication of Actemra for Cytokine Release Syndrome Induced by Cancer Treatment in Japan (Press release issued on February 28, 2023)
https://www.chugai-pharm.co.jp/english/news/detail/20230228150000_974.html

Chugai's Actemra Intravenous Infusion Receives Approval for Additional Indication and Dosing for Cytokine Release Syndrome (Press release issued on March 26, 2019)
https://www.chugai-pharm.co.jp/english/news/detail/20190326160001_600.html

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 cancer 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

###