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Chugai's Actemra Approved for Additional Indication of SARS-CoV-2 Pneumonia in Japan

- The approval is based on the results of several clinical studies in hospitalized patients with COVID-19.

TOKYO, January 21, 2022 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it obtained 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 the additional indication of the treatment of SARS-CoV-2 pneumonia (limited to patients requiring oxygen intervention). The approval came one month after the application for the additional indication on December 13, 2021.

"We are very pleased that Actemra, created by Chugai, has become a new treatment option for SARS-CoV-2 pneumonia. Clinical studies demonstrated that Actemra reduced the mortality rate in patients with SARS-CoV-2 infection," said Chugai's President and CEO, Dr. Osamu Okuda. "With the rapid spread of SARS-CoV-2 infection caused by Omicron strain, an increase is expected in the number of patients who become severely ill and develop pneumonia requiring oxygen intervention. We hope that Actemra will play a role for the better prognosis of patients with severe, potentially life-threating pneumonia."

This approval is based on the results from clinical studies evaluating Actemra in hospitalized patients, including an investigator-initiated, randomized, open-label, platform overseas study (RECOVERY study), three placebo-controlled, randomized, double-blind, multicenter global phase III studies conducted by Roche (COVACTA study, EMPACTA study, REMDACTA study), and a single-arm, multicenter phase III study in Japan (J-COVACTA study).

Actemra has been approved in the European Union, authorized for emergency use in the United States, and recommended by the World Health Organization for the treatment of COVID-19.

Package insert information *excerpt of revised part

Indications: SARS-CoV-2 pneumonia (limited to patients requiring oxygen intervention)

Dosage and administration: The usual adult dosage is a single intravenous infusion of 8 mg/kg tocilizumab (genetic recombination), in combination with corticosteroids. If symptoms do not improve, an additional single dose of 8 mg/kg tocilizumab (genetic recombination) may be administered 8 hours or more after the end of the initial administration.

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[Reference]

Chugai's Actemra/RoActemra Approved by the European Commission to Treat Patients with Severe COVID-19 (Dec 8, 2021)
https://www.chugai-pharm.co.jp/english/news/detail/20211208113000_879.html

Roche's Actemra/RoActemra receives U.S. FDA Emergency Use Authorization for the treatment of COVID-19 in hospitalised adults and children (Press release by Roche issued on June 25, 2021)
https://www.roche.com/media/releases/med-cor-2021-06-25.htm

Chugai Provides an Update on Phase III COVACTA Study of Actemra in Hospitalized Patients with Severe COVID-19 Associated Pneumonia (July 29, 2020)
https://www.chugai-pharm.co.jp/english/news/detail/20200729151500_752.html

Roche's phase III EMPACTA study showed Actemra/RoActemra reduced the likelihood of needing mechanical ventilation in hospitalised patients with COVID-19 associated pneumonia (Press release by Roche issued on September 18, 2020)
https://www.roche.com/media/releases/med-cor-2020-09-18.htm

Results of Phase III Clinical Study in Japan for Actemra in COVID-19 Associated Pneumonia (February 9, 2021)
https://www.chugai-pharm.co.jp/english/news/detail/20210209150000_803.html

Chugai Provides Update on the Phase III REMDACTA Study of Actemra Plus Remdesivir in Patients with Severe COVID-19 Pneumonia (March 11, 2021)
https://www.chugai-pharm.co.jp/english/news/detail/20210311150000_808.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 six indications in Japan: Castleman′s disease, rheumatoid arthritis, systemic juvenile idiopathic arthritis, polyarticular juvenile idiopathic arthritis, cytokine release syndrome induced by tumor-specific T cell infusion therapy, and adult Still's disease. In addition, Actemra subcutaneous injection is approved for three indications in Japan: rheumatoid arthritis, Takayasu arteritis, giant cell arteritis. Actemra has obtained regulatory approval in more than 110 countries worldwide.

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