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# Chugai Files for Additional Indication of Actemra for COVID-19 Pneumonia in Japan

- Application was filed based on the results of several clinical studies in hospitalized patients with COVID-19.

TOKYO, December 13 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it filed regulatory applications with 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 treatment of COVID-19 pneumonia.

"The spread of COVID-19 vaccination and the approval of several therapeutic drugs have played a major role in measures against the novel coronavirus. On the other hand, with the emergence of mutant strains such as the Omicron strain, the infection status remains to be unpredictable. In severe cases, symptoms can rapidly worsen and cause severe, life-threatening pneumonia. We will collaborate closely with the Japanese health authority to deliver Actemra to patients with COVID-19 pneumonia as soon as possible," said Chugai's President and CEO, Dr. Osamu Okuda.

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

The Actemra cohort of RECOVERY study evaluated the efficacy and safety of Actemra in combination with standard of care (Actemra group) compared to standard of care only (standard care group) in 4116 adult hospitalized patients with COVID-19 characterized by hypoxia and systemic inflammation. The Actemra group showed significant reduction of mortality rate by day 28, the primary endpoint, compared to standard care group (Actemra group: 31%, standard care group: 35%, rate ratio: 0.85, 95% confidence interval (CI): 0.76-0.94, p=0.0028). The proportion of patients discharged by day 28 was also higher in the Actemra group (Actemra group: 57%, standard care group: 50%, rate ratio: 1.22, 95% CI: 1.12-1.33, p<0.0001). There were no data suggesting that the treatment with Actemra increased deaths from infections other than COVID-19 or from other causes, and there were three serious adverse reactions for which a causal relationship to Actemra could not be ruled out (otitis externa, Staphylococcus aureus bacteremia, and pulmonary abscesses). No new safety signals were observed with Actemra treatment.

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

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[Reference]

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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