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Results of Phase III Clinical Study in Japan for Actemra in COVID-19 Associated Pneumonia

TOKYO, February 9, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced results from Phase III J-COVACTA clinical study in Japan 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]) in patients with COVID-19 associated pneumonia.

At 28 day after treatment 35 (72.9%) out of 48 patients treated with Actemra were discharged or became ready to be discharged from the hospital, and 5 (10.4%) experienced fatal outcome. 39 patients (81.3%) improved in at least one category on the 7-Category Ordinal scale at day 28 compared with the previous treatment. 6 patients (12.5%) worsened in at least one category. Safety for Actemra was consistent with its known safety profile and no new safety signals were identified. Further analysis of the study will be conducted, and the study results will be presented at a future medical meeting.

J-COVACTA study is a phase III single-arm clinical study conducted in Japan to investigate efficacy and safety of the combination of Actemra and standard of care in hospitalized patients with severe COVID-19 associated pneumonia. The primary endpoint is clinical status assessed using a 7-Category Ordinal Scale at day 28 after treatment. The Ordinal Scale ranges from one (discharged or ready to be discharged from hospital) to seven (death), defined based on the necessity of extracorporeal membrane oxygenation (ECMO) or mechanical ventilation and supplemental oxygen. Key secondary endpoints include time to clinical status improvement, and time to discharge or ready to discharge. The clinical trial notification was submitted on April 8, 2020. From May to October in 2020, a total of 49 patients were enrolled in the study.

Actemra has not been approved by any health authorities for the treatment of COVID-19 associated pneumonia. Several clinical studies conducted by Roche, including the phase III REMDACTA study in combination with remdesivir in hospitalized patients with severe COVID-19 associated pneumonia, are ongoing overseas. Results from the phase III COVACTA study in hospitalized patients with severe COVID-19 associated pneumonia were released in July 2020. In addition, results from the phase III EMPACTA study in hospitalized patients with COVID-19 associated pneumonia were released in September 2020.

Chugai will discuss the filing for additional indication of Actemra for the treatment of COVID-19 associated pneumonia with Japanese health authority based on results from J-COVACTA study and overseas studies including REMDACTA study.

[Reference]
Roche initiates phase III clinical trial of Actemra/RoActemra plus remdesivir in hospitalised patients with severe COVID-19 pneumonia (Press release by Roche issued on May 28, 2020)

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https://www.roche.com/media/releases/med-cor-2020-05-28.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

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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