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Chugai Provides an Update on Phase III COVACTA Study of Actemra in Hospitalized Patients with Severe COVID-19 Associated Pneumonia

- COVACTA study did not meet its primary endpoint of improved clinical status in patients with COVID-19 associated pneumonia, or the key secondary endpoint of reduced patient mortality
- The study is the first global randomized, double-blind, placebo-controlled phase III study investigating Actemra in this setting
- In collaboration with Roche, Chugai will continue clinical developments of Actemra for the treatment of severe COVID-19 associated pneumonia including in combination with antiviral drugs

TOKYO, July 29, 2020 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the phase III COVACTA study of Actemra® (tocilizumab) did not meet its primary endpoint of improved clinical status in hospitalized adult patients with severe COVID-19 associated pneumonia. In addition, the key secondary endpoints, which included the difference in patient mortality at week four, were not met; however, time to hospital discharge in patients treated with Actemra and placebo is 20 days and 28 days (median), respectively. COVACTA study did not identify any new safety signals for Actemra. Further analysis of the study results is needed to fully understand the data. The results will be submitted for publication in a peer-reviewed journal.

“COVID-19 is causing an unprecedented global crisis. Its primary endpoint was not achieved, however, we believe that this study has provided useful data on the efficacy and safety of Actemra's inhibition of IL-6 signaling in patients with severe COVID-19 associated pneumonia. We will analyze the data in detail to obtain new insights for future development programs.” said Chugai’s President and COO, Dr. Osamu Okuda.

The COVACTA study evaluated the safety and efficacy of intravenous Actemra added to standard-of-care treatment compared to treatment with placebo plus standard of care. The primary endpoint of clinical status in hospitalized adult patients with severe COVID-19 associated pneumonia was measured by a 7-category ordinal scale, which tracked patients’ clinical status based on the need for intensive care and/or ventilator use, as well as supplemental oxygen requirements. The COVACTA study is the first global randomized, double-blind, placebo-controlled phase III study to investigate Actemra in adult patients hospitalized with severe COVID-19 associated pneumonia, with study locations in the US, Canada and Europe.

Summary of COVACTA Key Clinical and Safety Findings

- Primary endpoint was not met. The difference in clinical status between Actemra and placebo in patients assessed using a 7-category ordinal scale at week four was not statistically significant (p=0.36; odds ratio [95% CI] = 1.19 [0.81,1.76], a statistically significant odds ratio greater than 1 would have favored Actemra).

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- Time to hospital discharge or ‘ready to discharge’ was shorter in patients treated with Actemra than in those treated with placebo. The median time to discharge or ‘ready to discharge’ for Actemra was 20 days and for placebo was 28 days (median time [95% CI]: Actemra = 20.0 [17.0,27.0]; placebo = 28.0 [20.0,NE], p=0.0370). However, the difference cannot be considered statistically significant as the primary endpoint was not met.
- The difference in ventilator-free days between Actemra and placebo was not statistically significant (median of 22 days for Actemra and 16.5 days with placebo, difference in medians [95% CI] = 5.5 [-2.8,13.0], p=0.3202).
- At week four, rates of infections were 38.3% and 40.6% in the Actemra and placebo arms respectively, and the rates of serious infections were 21.0% and 25.9% in the Actemra and placebo arms, respectively. The COVACTA study did not identify any new safety signals for Actemra.

In addition to COVACTA, Roche has initiated several studies to further investigate Actemra as a potential treatment for patients with COVID-19 associated pneumonia, including the REMDACTA study. There are also a number of independent studies of Actemra in this setting. Actemra has not been approved for COVID-19 associated pneumonia.

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

About the COVACTA study
COVACTA is a global, randomized, double-blind, placebo-controlled phase III study (COVACTA, NCT04320615) evaluating the safety and efficacy of intravenous Actemra added to standard of care in adult patients hospitalized with severe COVID-19 associated pneumonia compared to placebo plus standard of care. The primary and secondary endpoints include clinical status, mortality, mechanical ventilation and intensive care unit (ICU) variables at week four. Patients will be followed for 60 days post randomization.
There is no participation from Japan to the COVACTA study.

About Actemra
Actemra is the first therapeutic antibody created in Japan by Chugai, and designed to block the activity of IL-6, a type of inflammatory cytokine. First launched in June, 2005, the drug 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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