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Chugai Provides Update on the Phase III REMDACTA Study of Actemra Plus Remdesivir in Patients with Severe COVID-19 Pneumonia

- The REMDACTA study of Actemra plus remdesivir did not meet its primary endpoint of improved time to hospital discharge for patients with severe COVID-19 pneumonia or its key secondary endpoints compared to remdesivir alone
- The REMDACTA study results will be submitted to a peer reviewed journal

TOKYO, March 11, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) today announced that the global phase III randomized, double-blind, multicenter REMDACTA study of Actemra® (tocilizumab) plus remdesivir, versus placebo plus remdesivir, did not meet its primary endpoint. This was measured by improved time to hospital discharge up to day 28 in patients with severe COVID-19 pneumonia receiving standard of care. No new safety signals were identified for Actemra in the REMDACTA study.

“We are disappointed that REMDACTA study did not meet its endpoints, given the continued global pandemic of COVID-19. We will analyze overall data from clinical studies of Actemra for COVID-19 pneumonia including REMDACTA study in detail, and continue to further evaluate overall risk-benefit profile of Actemra in this setting,” said Chugai’s President and COO, Dr. Osamu Okuda.

The study did not meet key secondary endpoints, which included likelihood of death, likelihood of progression to mechanical ventilation or death, and clinical status. The full results of the study will be submitted for publication in a peer-reviewed journal later this year.

Chugai continues to evaluate data from the J-COVACTA, REMDACTA, COVACTA and EMPACTA studies as well as other studies of Actemra in COVID-19 pneumonia in collaboration with Roche. The EMPACTA study met its primary endpoint, while COVACTA study did not meet its primary endpoint. Both were recently published in the New England Journal of Medicine. The outcome of J-COVACTA study was released in February 2021.

Actemra is not approved for the treatment of COVID-19 pneumonia at the moment.

The antiviral medication remdesivir was invented and developed by Gilead Sciences and is approved or authorized for temporary use for the treatment of COVID-19 in approximately 50 countries worldwide.

[Reference]
・J-COVACTA study
Results of Phase III Clinical Study in Japan for Actemra in COVID-19 Associated Pneumonia (Feb 9, 2021)
https://www.chugai-pharm.co.jp/english/news/detail/20210209150000_803.html

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・COVACTA study
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

・EMPACTA study
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 REMDACTA study
REMDACTA is a two-armed global phase III, randomized, double-blind, multicenter study (REMDACTA, NCT04409262) to evaluate the efficacy and safety of Actemra plus remdesivir, versus placebo plus remdesivir in hospitalized patients with severe COVID-19 pneumonia receiving standard of care. Remdesivir is an antiviral medicine that works to stop replication of SARS-CoV-2, the virus that causes COVID-19. The REMDACTA study is being conducted by Roche in collaboration with Gilead Sciences, Inc. The enrollment of the study was increased from 450 patients globally to 650 patients to ensure a more robust data set. The primary endpoint of the study is improvement in time to hospital discharge by Day 28. Key secondary endpoints include likelihood of death, likelihood of progression to mechanical ventilation or death, and clinical status. Clinical status is measured by the 7-category ordinal scale, which tracks patients' clinical status based on the need for intensive care and/or ventilator use, as well as supplemental oxygen requirements. Patients will be followed for 60 days post-randomization.

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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