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Japan to offer Actemra for treating COVID-19 patients

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Chugai Pharmaceutical has 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.

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.