

Chugai Starts Phase III Clinical Trial of Actemra for COVID-19 Pneumonia in Japan

TOKYO, April 8, 2020 -- <u>Chugai Pharmaceutical Co., Ltd.</u> (TOKYO: 4519) announced that it is working to start a Phase III clinical trial in Japan with 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 COVID-19 pneumonia.

Chugai filed a clinical trial notification with the Pharmaceuticals and Medical Devices Agency today to conduct a Phase III clinical trial of Actemra for the treatment of hospitalized patients with severe COVID-19 pneumonia in Japan. It is working to start enrolling as soon as possible after finalizing study details.

Roche announced to initiate a randomized, double-blind, placebo-controlled Phase III clinical trial (COVACTA study) globally including the U.S., Canada and Europe to evaluate the safety and efficacy of Actemra plus standard of care in hospitalized patients with severe COVID-19 pneumonia compared to placebo plus standard of care.

[Reference]

Roche initiates Phase III clinical trial of Actemra/RoActemra in hospitalised patients with severe COVID-19 pneumonia (Mar 19, 2020)

https://www.roche.com/media/releases/med-cor-2020-03-19.htm

Genentech Announces FDA Approval of Clinical Trial for Actemra to Treat Hospitalized Patients With Severe COVID-19 Pneumonia (Mar 23, 2020)

https://www.gene.com/media/press-releases/14843/2020-03-23/genentech-announces-fda-approval-of-clin

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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