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Taiwan approves Japan-based Chugai Pharma's drug for COVID-19 treatment

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Actemra is the first therapeutic antibody created in Japan by Chugai

Chugai Pharma Taiwan Ltd., a wholly-owned subsidiary of Japan's Chugai Pharmaceutical, has obtained an import drug license from the Taiwan Food and Drug Administration (TFDA) for Chugai's Actemra (tocilizumab) intravenous (IV) formulation for the treatment of COVID-19 in hospitalised adult patients who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

This approval is based on the results from clinical studies evaluating Actemra in hospitalised patients, including an investigator-initiated, randomised, open-label, platform overseas study (RECOVERY study) and three placebo-controlled, randomized, double-blind, multicenter, global phase III studies conducted by Roche (COVACTA study, EMPACTA study, REMDACTA study).

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 seven 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, adult Still's disease, and SARS-CoV-2 pneumonia.

In addition, Actemra subcutaneous injection is approved for three indications in Japan: rheumatoid arthritis, Takayasu arteritis, and giant cell arteritis. Actemra has obtained regulatory approval in more than 110 countries worldwide.