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Chugai's Actemra/RoActemra Approved by the European Commission to Treat Patients with Severe COVID-19

- Approval granted immediately after EMA's CHMP recommendation for approval
- Approval based on results from four phase III studies in over 5,500 patients

TOKYO, December 8, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Roche has received notification that the European Commission has extended the marketing authorization for Actemra®/RoActemra® (tocilizumab) to include the treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation. This decision comes just hours after the recommendation by the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP), reflecting the urgent need for Actemra/RoActemra as a potential treatment option during the COVID-19 public health emergency.

"We are very pleased that Actemra/RoActemra has been rapidly approved as a new treatment for people with severe COVID-19. In Europe, the resurgence of COVID-19 and the impact of the Omicron strain are causing further concern. We hope that Actemra/RoActemra will play a major role in the treatment of patients with severe disease in which different care is needed according to the patient's condition," said Chugai's President and CEO, Dr. Osamu Okuda.

The decision from the European Commission follows an accelerated assessment by the EMA's CHMP which reviewed results from four studies of Actemra/RoActemra in over 5,500 patients with severe or critical COVID-19. These include the Roche-led phase III COVACTA, EMPACTA and REMDACTA trials, and the University of Oxford's Randomized Evaluation of COVID-19 Therapy (RECOVERY) study, which was supported by Roche.

Outside of the European Union, Actemra/RoActemra has been provisionally approved in Australia, authorized for emergency use in some countries and Ghana, and recommended by the World Health Organization (WHO) for the treatment of COVID-19.

Following the recent emergence of the new SARS-CoV-2 variant of concern, Omicron (B.1.1.529), WHO has reported that interleukin 6 receptor blockers, such as Actemra/RoActemra, are expected to still be effective for managing patients with severe COVID-19

[Reference]
Roche's Actemra/RoActemra receives U.S. FDA Emergency Use Authorization for the treatment of COVID-19 in hospitalised adults and children (Press release by Roche issued on June 25, 2021)
https://www.roche.com/media/releases/med-cor-2021-06-25.htm

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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

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

Results of Phase III Clinical Study in Japan for Actemra in COVID-19 Associated Pneumonia (February 9, 2021)
https://www.chugai-pharm.co.jp/english/news/detail/20210209150000_803.html

Chugai Provides Update on the Phase III REMDACTA Study of Actemra Plus Remdesivir in Patients with Severe COVID-19 Pneumonia (March 11, 2021)
https://www.chugai-pharm.co.jp/english/news/detail/20210311150000_808.html

About Actemra/RoActemra

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

Source
World Health Organization. Update on Omicron. Available from: https://www.who.int/news/item/28-11-2021-update-on-omicron. Accessed December 2021.

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