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CHMP Recommends EU Approval of Chugai's Actemra/RoActemra to Treat Patients with Severe COVID-19

- Actemra/RoActemra reduced the risk of death in patients with severe COVID-19, as evidenced by a review of four phase III studies

TOKYO, December 7, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Roche has received notification that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has recommended extending the marketing authorization for the humanized anti-human IL-6 receptor monoclonal antibody Actemra®/RoActemra® (tocilizumab) to include the treatment of COVID-19 in adults who are receiving systemic corticosteroids and require supplemental oxygen or mechanical ventilation.

"Actemra/RoActemra came a step closer to the approval for the treatment of severe COVID-19 in Europe. Earlier this year, the CHMP had granted accelerated assessment for Actemra/RoActemra as a drug that may significantly contribute to public health. As the symptoms of COVID-19 vary from patient to patient, expansion of treatment options is critically important. We believe that Actemra/RoActemra, which has shown therapeutic efficacy in severe COVID-19 from the totality of clinical evidence, will become a key treatment option for the treatment of severe disease," said Chugai's President and CEO, Dr. Osamu Okuda.

In August 2021, the EMA's CHMP began an accelerated assessment of Actemra/RoActemra – this rapid analysis is reserved for medicines that may offer significant benefit to public health. The assessment reviewed results from four studies 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. The totality of this clinical evidence demonstrated that Actemra/RoActemra reduced the risk of death in patients with severe or critical COVID-19.

Actemra/RoActemra has been provisionally approved in Australia, authorized for emergency use in the United States and Ghana, and recommended by the World Health Organization 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

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[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

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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