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U.S. FDA Grants Priority Review to Chugai's Actemra/RoActemra for the Treatment of COVID-19 in Hospitalized Adults

- U.S. FDA accepted Genentech's application for Chugai's anti-IL-6 receptor antibody Actemra/RoActemra for the treatment of COVID-19 in hospitalized adults, granting priority review
- Since the beginning of the pandemic, more than one million people hospitalized with COVID-19 have been treated with Actemra/RoActemra worldwide[1]
- If approved, Actemra/RoActemra would be the first FDA-approved immunomodulator for the treatment of COVID-19 in hospitalized patients
- Actemra/RoActemra is approved for the treatment of COVID-19 in many countries including Japan and the European Union.

TOKYO, April 4, 2022 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that the U.S. Food and Drug Administration (FDA) has accepted the supplemental Biologics License Application (sBLA) and has granted Priority Review for the humanized anti-human IL-6 receptor monoclonal antibody Actemra®/RoActemra® [generic name: tocilizumab (genetical recombination)] intravenous (IV) for the treatment of COVID-19 in hospitalized adults who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO). The sBLA was filed by Genentech Inc., a member of Roche Group. A decision on FDA approval is expected in the second half of this year.

"We are very pleased that Actemra, which has been used in the U.S. under the Emergency Use Authorization, has made a step forward toward the regulatory approval by the U.S. FDA," said Chugai's President and CEO, Dr. Osamu Okuda. "Actemra has proven clinical benefits for severe COVID-19 and has contributed to the treatment of more than one million patients worldwide as one of the key treatment options. We will continue to work together with Roche as the first FDA-approved immunomodulator for severely ill patients."

The sBLA submission is based on results from four randomized, controlled studies that evaluated Actemra/RoActemra for the treatment of COVID-19 in more than 5,500 hospitalized patients. Altogether, the results of these four studies (COVACTA, EMPACTA, REMDACTA, and RECOVERY) suggest that Actemra/RoActemra may improve outcomes in patients receiving corticosteroids and requiring supplemental oxygen or breathing support.[2-5]

In June 2021, Actemra/RoActemra received Emergency Use Authorization from the U.S. FDA and is currently approved for use in 16 countries around the world for defined patients hospitalized with severe or critical COVID-19.[6,7] In February 2022, the World Health Organization (WHO) prequalified Actemra/RoActemra for patients with severe COVID-19, supporting access to care in low- and middle-income countries.[8]

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Following the emergence of the SARS-CoV-2 variant of concern, Omicron (B.1.1.529), in December 2021 WHO reported that IL-6 receptor blockers, such as Actemra/RoActemra, are expected to be still effective for managing patients with severe COVID-19.[9]

[Reference]
WHO grants prequalification of Actemra/RoActemra for patients with severe or critical COVID-19 (Press release by Roche issued on February 11, 2022)
https://www.roche.com/media/releases/med-cor-2022-02-11b

Chugai's Actemra Approved for Additional Indication of SARS-CoV-2 Pneumonia in Japan (Jan 21, 2022)
https://www.chugai-pharm.co.jp/english/news/detail/20220121160000_892.html

Chugai's Actemra/RoActemra Approved by the European Commission to Treat Patients with Severe COVID-19 (Dec 8, 2021)
https://www.chugai-pharm.co.jp/english/news/detail/20211208113000_879.html

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 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

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

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

About Actemra

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 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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Source

1. Roche data on file; Between March 2020 and December 2021 based on Actemra IV dosing for C-19 (8mg per kg or 2 X 400 mg eq vial)
2. Rosas IO, et al. Tocilizumab in Hospitalized Patients with Severe Covid-19 Pneumonia. NEJM. 2021;384:1503-16.
3. Salama C, et al. Tocilizumab in Patients Hospitalized with Covid-19 Pneumonia. NEJM. 2021;384:20-30.
4. Rosas IO, et al. Tocilizumab and remdesivir in hospitalized patients with severe COVID-19 pneumonia: a randomized clinical trial. Intensive Care Med. 2021;47:1258–70.
5. Horby P, et al. Tocilizumab in patients admitted to hospital with COVID-19 (RECOVERY): preliminary results of a randomised, controlled, open-label, platform trial. Lancet. 2021;397(10285):1637-1645.
6. U.S. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Drug for Treatment of COVID-19. Available from: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-drug-treatment-covid-19. Accessed March 2022.
7. Roche data on file.
8. World Health Organization. WHO prequalifies first monoclonal antibody – tocilizumab – to treat COVID-19. Available from: https://www.who.int/news/item/11-02-2022-who-prequalifies-first-monoclonal-antibody---tocilizumab-to-treat-covid-19. Accessed March 2022.
9. World Health Organization. Update on Omicron. Available from: https://www.who.int/news/item/28-11-2021-update-on-omicron. Accessed March 2022.

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