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Chugai Files New Drug Application in Japan for Antibody Cocktail Casirivimab and Imdevimab for the Treatment of COVID-19

- The application is based on the results from a global phase III study in patients with COVID-19 and a phase I study in Japanese.
- The application seeks the Special Approval for Emergency.

TOKYO, June 29, 2021 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that it filed a new drug application with the Ministry of Health, Labour and Welfare (MHLW) for the antibody cocktail casirivimab and imdevimab for the treatment of COVID-19. The application seeks the Special Approval for Emergency.

“The COVID-19 pandemic, including the spread of infections of variants, has been persistent, and new treatment options are needed. The antibody cocktail casirivimab and imdevimab significantly reduced the risk of hospitalization or death in high-risk, non-hospitalized patients with COVID-19 in a global phase III clinical study,” said Chugai’s President and CEO, Dr. Osamu Okuda. “We will collaborate closely with Japanese health authority to deliver this antibody cocktail as a new treatment to patients as soon as possible.”

This application is based on the results from the global phase III clinical study (REGN-COV 2067 study) in patients with COVID-19 and a phase I clinical study to examine the safety, tolerability, and pharmacokinetics in Japanese.

The antibody cocktail combining two virus-neutralizing antibodies, casirivimab and imdevimab, is developed by U.S.-based Regeneron and Roche for the potential treatment and prevention of COVID-19. In August 2020, both companies announced a collaboration to develop, manufacture and distribute the antibody cocktail. In December of the same year, Chugai obtained development and exclusive commercialization rights in Japan from Roche.

<Reference>

Chugai Reached Agreement with Japanese Government regarding Investigational Antibody Cocktail (casirivimab and imdevimab) for COVID-19 (Press release by Chugai issued on May 10, 2021)
https://www.chugai-pharm.co.jp/english/news/detail/20210510150000_821.html

New phase III data shows investigational antibody cocktail casirivimab and imdevimab reduced hospitalisation or death by 70% in non-hospitalised patients with COVID-19 (Press release by Roche issued on March 23, 2021)
https://www.roche.com/media/releases/med-cor-2021-03-23.htm

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Chugai in-licenses Antibody Cocktail for COVID-19 from Roche (Press release by Chugai issued on December 10, 2020)
https://www.chugai-pharm.co.jp/english/news/detail/20201210170001_785.html

About casirivimab and imdevimab

Casirivimab and imdevimab were designed specifically by Regeneron scientists to block the infectivity of SARS-CoV-2, the virus that causes COVID-19. They evaluated thousands of fully-human antibodies produced by the company's proprietary VelocImmune® mice, which have been genetically-modified to have a human immune system, as well as antibodies identified from humans who have recovered from COVID-19. The two potent, virus-neutralizing antibodies that form casirivimab and imdevimab are believed to bind non-competitively to the critical receptor binding domain of the virus's spike protein, which may help diminish the ability of mutant viruses to escape treatment and protects against spike variants that have arisen in the human population[1]. Casirivimab and imdevimab have not been approved by any health authority.

About the Special Approval for Emergency

Under article 14-3, Paragraph 1 of the Act on Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices, the Minister of Health, Labour and Welfare may approve a certain medical product that meets the following criteria, upon discussion with the Pharmaceutical Affairs and Food Sanitation Council:

1) An emergency situation requires an unapproved medical product to be used to prevent damage to the public health caused by the spread of diseases, and such emergency situation cannot be managed appropriately by any means other than the use of the unapproved product;
2) Such product is legally available in a country with a regulatory system for medical products that is equivalent to Japan

Source

1. Alina Baum, Benjamin O Fulton, Elzbieta Wloga, et al. Science 2020 Aug 21;369(6506):1014-1018.

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