July 20, 2021

Name of listed company:	Chugai Pharmaceutical Co., Ltd.
Code number:	4519 (1st Section of Tokyo Stock Exchange)
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The Antibody Cocktail, RONAPREVE for Intravenous Infusion Set Receives the World's First Regulatory Approval from MHLW for COVID-19

- Ronapreve obtained regulatory approval for the first treatment of mild to moderate COVID-19, with the application of the Special Approval for Emergency
- In a global phase III clinical trial, Ronapreve showed suppression of aggravation and shortened time to the symptoms resolution by a single administration
- In order to ensure appropriate and timely supply of Ronapreve, Chugai will work closely with the Japanese government and all related business partners

TOKYO, July 20, 2021-- Chugai Pharmaceutical Co., Ltd. announced that it obtained regulatory approval from the Ministry of Health, Labour and Welfare (MHLW) for the anti-SARS-CoV-2 monoclonal antibody RONAPREVE for Intravenous Infusion Set 300 and Set 1332 [generic name: Casirivimab (genetical recombination) /Imdevimab (genetical recombination)] for the indication of SARS-CoV-2 infection on July 19. The Special Approval for Emergency under article 14-3 of the Pharmaceuticals and Medical Devices Act was applied to this approval.

"The COVID-19 pandemic has entered a new phase with the emergence of multiple variants, and in order to bring the pandemic under control as soon as possible, it is extremely important to prevent new infections with vaccines and to expand the treatment options for people with COVID-19. Ronapreve reduced the risk of hospitalization or death, leading to suppression of aggravation and shortened time to the symptoms resolution for high-risk outpatients in a clinical study," said Dr. Osamu Okuda, Chugai's President and CEO. "Also, Ronapreve is confirmed to be effective for the multiple variants including Delta variant in non-clinical studies. Based on this evidence, the drug received Special Approval for Emergency, due to its urgent need to prevent the spread of diseases. We will work closely with the Japanese government and all related business partners to ensure prompt supply of the drug amid the ongoing spread of infection."

This approval 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.

Under the agreement with the Japanese government, the domestic supply of Ronapreve is secured for use in 2021. We will continue to collaborate with the Japanese government to ensure an appropriate and timely supply of the antibody cocktail.

Combining two virus-neutralizing antibodies, casirivimab and imdevimab, Ronapreve has been created by Regeneron (U.S.) for the potential treatment and prevention of COVID-19. In August 2020, Regeneron and Roche announced a collaboration to manufacture, develop and distribute the antibody cocktail. In December of the same year, Chugai obtained development and exclusive commercialization rights in Japan from Roche. Ronapreve has not been approved in countries other than Japan at the moment.

Approval Information

Product name:	RONAPREVE for Intravenous Infusion Set 300／RONAPREVE for Intravenous Infusion Set 1332
Generic name:	casirivimab (genetical recombination) ／imdevimab (genetical recombination)
Indications:	SARS-CoV-2 infection
Dosage and administration:	The usual dose for adults and children aged 12 years and older and weighing 40 kg or more is 600 mg casirivimab (genetical recombination) and 600 mg imdevimab (genetical recombination) given as a single intravenous dose.

[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

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 Ronapreve:

Ronapreve was 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].

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 public health caused by the spread of diseases, and such emergency 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

VelocImmune® is protected by law.

Source:

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

This matter is not included in the earnings forecast for the fiscal year 2021 announced on February 4, 2021. No changes are expected to Chugai's financial prospects at this time, but we will promptly disclose any events that should be disclosed in the future.

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