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ASIA EDITION

Japan approves Regeneron's antibody cocktail for COVID-19 treatment

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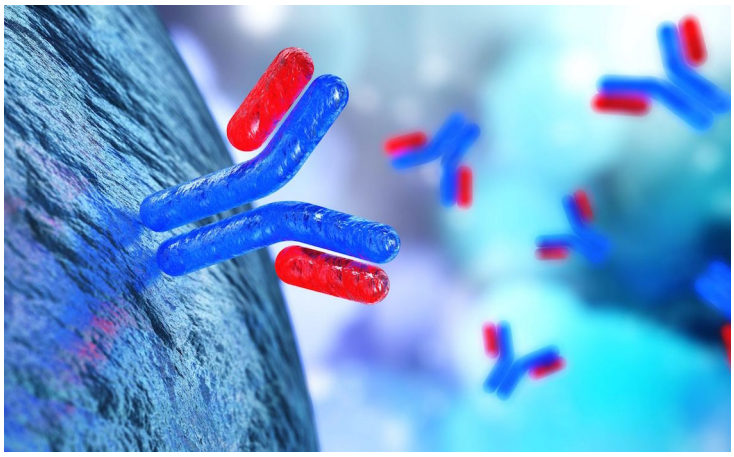
The approval was based on results from a Phase 3 trial in high-risk non-hospitalized patients



US-based Regeneron Pharmaceuticals has announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved Regeneron's casirivimab and imdevimab antibody cocktail to treat patients with mild to moderate COVID-19.

This marks the first time the antibody cocktail, known as REGEN-COV™ in the U.S. and Ronapreve™ in other countries, has received a full approval to treat COVID-19.

Emergency or temporary pandemic use authorizations are currently in place in more than 20 countries, including in the U.S., European Union, India, Switzerland and Canada.

In Japan, the antibody cocktail was granted a Special Approval Pathway under article 14-3 of the Pharmaceuticals and Medical Devices Act. The approval was based on results from a Phase 3 trial in high-risk non-hospitalized patients, which showed the antibody cocktail reduced the risk of hospitalization or death by 70%, as well as results from a Phase 1 trial that examined the safety, tolerability and pharmacokinetics in Japanese people.

Regeneron invented REGEN-COV and is collaborating with Roche to increase global supply of the antibody cocktail, with Roche primarily responsible for development and distribution outside the U.S.

In December 2020, Japanese firm Chugai obtained development and exclusive commercialization rights in Japan from Roche, and is working with the Japanese government to ensure an appropriate and timely supply of the antibody cocktail.