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Korea fully approves first monoclonal antibody treatment for COVID-19

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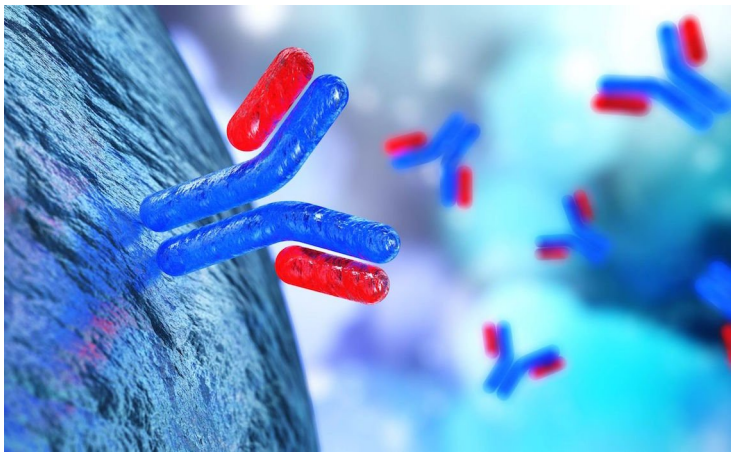
The approval marks the first time a monoclonal antibody treatment for COVID-19 received full approval



Celltrion Group has announced that the Korean Ministry of Food and Drug Safety (MFDS) has approved regdanvimab (CT-P59), a monoclonal antibody treatment for COVID-19 for the extended use in elderly patients aged 50 years and over, or with at least one underlying medical condition (the obese, cardiovascular disease, chronic lung disease, diabetes, chronic kidney disease, chronic liver disease, and patients with immunosuppressive agents) with mild symptoms of COVID-19, and adult patients with moderate symptoms of COVID-19.

This marks the first time a monoclonal antibody treatment for COVID-19 has received a full approval to treat patients with COVID-19 from the Korean MFDS.

In February, the Korean MFDS granted a Conditional Marketing Authorisation (CMA) for the emergency use of regdanvimab (CT-P59) and allowed the use of CT-P59 in adult patients aged 60 years and over, or with at least one underlying medical condition (cardiovascular, chronic respiratory disease, diabetes, high blood pressure) with mild symptoms of COVID-19, and adult patients with moderate symptoms of COVID-19.

The administration time for the recommended dosage of regdanvimab (CT-P59), a single intravenous (IV) infusion of 40 mg/kg, has been reduced from 90 minutes to 60 minutes.