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Celltrion initiates Ph I trial for COVID-19 drug in Korea

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The Korean Ministry of Food and Drug Safety (MFDS) approved Celltrion's Investigational New Drug (IND) application to initiate a Phase I trial of CT-P59 in patients



Celltrion Group has announced that the Korean Ministry of Food and Drug Safety (MFDS) has approved the company's Investigational New Drug (IND) application for a Phase I clinical trial of CT-P59, a COVID-19 antiviral antibody treatment candidate. Celltrion has initiated enrolment of patients with mild symptoms of SARS-CoV-2 infection and the clinical trial is set to evaluate the safety, tolerability, efficacy, pharmacokinetics and immunogenicity of CT-P59.

Celltrion anticipates global pivotal study results from the Phase II and III trials in patients with mild symptoms, the Phase III trial in patients with moderate-to-severe COVID-19, and the prevention clinical trial, by the end of the year.

Celltrion plans to enrol people that are in close contact with COVID-19 patients and those with no symptoms as part of a prevention clinical trial to evaluate whether CT-P59 can elicit a neutralising antibody response to prevent the virus from infecting human cells.

In July, Celltrion initiated a Phase I trial of CT-P59 in the UK following the approval of the clinical trial authorisation (CTA) application from the UK Medicines and Healthcare products Regulatory Agency (MHRA). Celltrion has also completed an infusion and initial safety assessment for the Phase I study in healthy volunteers in Korea and the study is set for completion by Q3 this year as originally planned.