BioSpectrum the business of Bio & Health Sciences ASIA EDITION

0

23 September 2020 | News

The global Phase II/III trial is set to enrol 1,000 patients from up to 12 countries to investigate the safety and efficacy of CT-P59

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 II/III pivotal clinical trial of CT-P59, an anti-COVID-19 monoclonal antibody (mAb) treatment candidate.

The global trial will evaluate the safety and efficacy of CT-P59 in patients with mild-to-moderate symptoms of SARS-CoV-2 infection. Celltrion is set to obtain the summary of the primary results for Phase II of the study by the end of the year.

Celltrion has submitted the IND application for the clinical trial in 6 countries including Korea, the U.S and Spain, and plans to enrol more than 1,000 patients from up to 12 countries. The company expects to be able to apply for emergency use authorisation (EUA), conditional on the results of the pivotal trial.

Celltrion has begun manufacturing the process validation batch of CT-P59 and plans to increase manufacturing capabilities to meet the current global and domestic demand for the anti-COVID-19 monoclonal antibody treatment candidate.

As part of its efforts to address the pandemic, Celltrion has also initiated an ongoing in-human global Phase I clinical trial of CT-P59 in mild COVID-19 patients, and plans to investigate the use of CT-P59 as a preventative treatment for COVID-19 in those in close contact with COVID-19 patients as part of a prevention clinical trial.