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Korea approves first anti-COVID-19 monoclonal antibody treatment

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CT-P59 is approved for the treatment of patients aged 60 years and over, or with at least one underlying medical condition, with mild symptoms of COVID-19, and adult patients with moderate symptoms of COVID- 19

Celltrion Group has announced that the Ministry of Food and Drug Safety (MFDS) of South Korea has granted conditional marketing authorization (MA) for the emergency use of regdanvimab (CT-P59), an anti-COVID-19 monoclonal antibody treatment candidate. Conditional Marketing Authorization allows emergency 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, elevated blood pressure) mild symptoms of COVID-19, and in adult patients with moderate symptoms of COVID-19.

The conditional MA is based on Part 1 of the Phase II / III trial and showed the following results:

- Patients treated with CT-P59 showed a significant reduction in the risk of hospitalization and oxygenation related to COVID-19 through day 28
- Rates of progression to severe COVID-19 reduced by 54% for patients with mild to moderate symptoms and 68% for patients with moderate symptoms aged 50 and over
- A significant reduction (between 3.4 and 6.4 days) in the duration of clinical recovery in patients treated with CT-P59 (40 mg / kg) compared to placebo.

“ With the pandemic still raging in Korea, we believe this conditional marketing authorization for regdanvimab represents an important step in the fight against COVID-19,” says Dr HoUng Kim, Ph.D., head of the medical and marketing division of Celltrion Healthcare.

A global Phase III clinical trial is being recruited (1,172 patients planned) for mild to moderate symptoms of COVID-19 at more than 10 sites worldwide to assess the efficacy and safety results of CT -P59. Celltrion is in the process of demonstrating clinical efficacy against COVID-19 for the British and South African variants. The results are expected in the coming days.