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October 19, 2021

Notification of premature termination of the CT-P59 3.1 Study

Protocol number:	CT-P59 3.1
Protocol Title:	A Phase 2/3, Randomized, Parallel-Group, Placebo-Controlled, Double-Blind Study to Evaluate the Efficacy and Safety of CT-P59 in Combination with Standard of Care in Hospitalized Patients with SARS-CoV-2 Infection

To whom it may concern,

Please be informed that our CT-P59 3.1 study has prematurely terminated due to several reasons.

First of all, it has been concluded by CELLTRION's expertise that CT-P59 study drug has more benefit for early stage COVID-19 patients rather than severe patients with SARS-CoV-2 Infection. As this study is targeted for severe COVID-19 patients, it has been determined that CELLTRION is no longer able to continue the study.

Moreover, CELLTRION was concerned on the process of subject recruitment. Several barriers were anticipated to succeed in recruiting and enrolling the eligibility criteria-met patients since severe COVID-19 patients should be randomized in this study. CELLTRION thought that these barriers would lead to a burden for investigators and also impact the whole study timeline which CELLTRION certainly would want to avoid.

In conclusion, this study has ended prematurely and it is the reason for not posting results in EudraCT.

Yours Sincerely,

DongHun Lee
Clinical Operations Team
CELLTRION, Inc.
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