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Shionogi files for approval of COVID-19 drug in Japan

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Shionogi Files for approval of S-217622, a therapeutic drug for COVID-19, in Japan

Japanese firm Shionogi has completed the analysis of primary endpointsin the Phase 2b part of a Phase 2/3 clinical trial of S-217622, an orally administered antiviral drug for COVID-19, and has filed for manufacture and sales approval, requesting review under the conditional approval system in Japan.

This Phase 2b part of the Phase 2/3 clinical trial is a randomized, placebo-controlled, double-blind study in 428 SARS-CoV-2 infected subjects with mild/moderate symptoms (419 in Japan and 9 in South Korea). This study was conducted mainly in infected patients after the Omicron variant wave of the epidemic, and its main purpose is to confirm the antiviral effect and clinical symptom improvement of S-217622 (2 dose groups) when orally administered once daily for 5 days. The main results are outlined below.

Shionogi will promptly submit further analyses of the data from this study to the Pharmaceuticals and Medical Devices Agency (PMDA) so that we can provide this therapeutic drug in Japan as early as possible. In parallel, Shionogi will accelerate the ongoing Phase 3 part of the study in patients with mild/moderate symptoms (target subject number: 1,260) and Phase 2b/3 part of the study in patients with asymptomatic/only mild symptoms (target subject number: 300 to 600) and will submit those data sequentially to the PMDA, as they are obtained.