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Gilead Initiates Ph 3 trials of remdesivir for COVID-19

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U.S. FDA Grants Investigational New Drug Authorization to Study Remdesivir for the Treatment of COVID-19

Gilead Sciences, has announced the initiation of two Phase 3 clinical studies to evaluate the safety and efficacy of remdesivir in adults diagnosed with COVID-19 (novel coronavirus). These randomized, open-label, multicenter studies will enroll approximately 1,000 patients at medical centers primarily across Asian countries, as well as other countries globally with high numbers of diagnosed cases, beginning in March.

The studies will assess two dosing durations of remdesivir, administered intravenously. The initiation of these studies follows the U.S. Food and Drug Administration's (FDA) rapid review and acceptance of Gilead's investigational new drug (IND) filing for remdesivir for the treatment of COVID-19.

The new clinical studies expand the ongoing research into remdesivir, which includes two clinical trials in China's Hubei province led by the China-Japan Friendship Hospital as well as the recently initiated clinical trial in the United States led by the National Institute of Allergy and Infectious Diseases (NIAID). Gilead has donated drug and provided scientific input for these studies, with results from those in China expected in April.

"Gilead's primary focus is on rapidly determining the safety and efficacy of remdesivir as a potential treatment for COVID-19, and this complementary array of studies helps to give us a more expansive breadth of data globally on the drug's profile in a short amount of time. The speed with which remdesivir has moved into clinical development for this coronavirus reflects the pressing need for treatment options and the shared commitment of industry, governments, global health organizations and healthcare providers to respond to this public health threat with the highest urgency," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences.

The Gilead studies will evaluate two dosing durations of remdesivir. One study will randomize approximately 400 patients with severe clinical manifestations of COVID-19 to receive either five or 10 days of remdesivir. The second study will randomize approximately 600 patients with moderate clinical manifestations of disease to receive five or 10 days of remdesivir or standard of care alone. The primary endpoint of both studies is clinical improvement, as described below.

Remdesivir is not yet licensed or approved anywhere globally and has not been demonstrated to be safe or effective for any use. Working with government agencies, non-governmental organizations and local regulatory authorities, Gilead is providing

remdesivir to qualified patients with COVID-19 on a compassionate use basis for emergency treatment outside of ongoing clinical studies.