



Gilead Sciences Initiates Two Phase 3 Studies of Investigational Antiviral Remdesivir for the Treatment of COVID-19

February 26, 2020

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

FOSTER CITY, Calif.--(BUSINESS WIRE)--Feb. 26, 2020-- Gilead Sciences, Inc. (Nasdaq: GILD) today 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.

For more information on Gilead's response to the coronavirus outbreak please visit the company's dedicated page: <https://www.gilead.com/purpose/advancing-global-health/covid-19>

About Remdesivir

Remdesivir is an investigational nucleotide analog with broad-spectrum antiviral activity both in vitro and in vivo in animal models against multiple emerging viral pathogens including Ebola, Marburg, MERS and SARS. Remdesivir has been studied in healthy volunteers and in people with Ebola virus infection. Individual compassionate use cases are not sufficient to determine the safety and efficacy of remdesivir in treating COVID-19, which can only be determined through prospective clinical trials.

About Gilead-Sponsored New Remdesivir Clinical Trials

The first of two studies will evaluate the safety and efficacy of both a 5-day and a 10-day dosing regimen of remdesivir administered intravenously in patients with severe manifestations of COVID-19. Approximately 400 participants will be randomized in a 1:1 ratio to receive remdesivir 200 mg on day one, followed by remdesivir 100 mg each day until day 5 or 10, in addition to standard of care. The primary objective of this study is to evaluate the effect of remdesivir, as measured by the normalization of fever and oxygen saturation [$T < 36.6^{\circ}\text{C}$ armpit, $< 37.2^{\circ}\text{C}$ oral, $< 37.8^{\circ}\text{C}$ rectal; and $\text{SpO}_2 > 94\%$, sustained for at least 24 hours through Day 14].

The second study will evaluate the safety and efficacy of a 5-day and a 10-day dosing regimen of remdesivir administered intravenously in patients with moderate manifestations of COVID-19, compared with standard of care. Approximately 600 participants will be randomized in a 1:1:1 ratio to receive remdesivir 200 mg on day one, followed by remdesivir 100 mg in addition to standard of care each day until day 5 or 10, compared with standard of care alone. The primary objective of this study is to evaluate the effect of remdesivir, as measured by the proportion of participants in each group discharged by day 14.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. For more information on Gilead Sciences, please visit the company's website at www.gilead.com.

Forward Looking Statement

This press release includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the possibility of unfavorable results from clinical trials involving remdesivir and the possibility that we may be unable to complete one or more of such trials in the currently anticipated timelines or at all. Further, it is possible that Gilead may make a strategic decision to discontinue development of remdesivir. As a result, remdesivir may never be successfully commercialized. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could

cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

For more information on Gilead Sciences, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.

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