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For Immediate Release

DATA ON 53 PATIENTS TREATED WITH INVESTIGATIONAL ANTIVIRAL REMDESIVIR THROUGH THE COMPASSIONATE USE PROGRAM PUBLISHED IN NEW ENGLAND JOURNAL OF MEDICINE

-- Remdesivir treatment resulted in clinical improvement in 68 percent of patients in this limited data set --

Foster City, Calif., April 10, 2020– Gilead Sciences, Inc. (Nasdaq: GILD) today announced results from a cohort analysis of 53 patients hospitalized with severe complications of COVID-19 who were treated with the investigational antiviral remdesivir on an individual compassionate use basis. The majority of patients in this international cohort demonstrated clinical improvement and no new safety signals were identified with remdesivir treatment. Compassionate use data have limitations and multiple Phase 3 studies are ongoing to determine the safety and efficacy of remdesivir for the treatment of COVID-19. The detailed results of this analysis were published today in *The New England Journal of Medicine*.

Remdesivir is not yet licensed or approved anywhere globally and has not been demonstrated to be safe or effective for the treatment of COVID-19.

Nearly two thirds of patients (64 percent, n=34/53) in this cohort were on mechanical ventilation at baseline, including four patients also on extracorporeal membrane oxygenation (ECMO). Treatment with remdesivir resulted in an improvement in oxygen support class for 68 percent of patients (n=36/53) over a median follow-up of 18 days from the first dose of remdesivir. More than half of patients on mechanical ventilation were extubated (57 percent, n=17/30) and nearly half of all patients (47 percent, n=25/53) were discharged from the hospital following treatment with remdesivir. After 28 days of follow-up, the cumulative incidence of clinical improvement, defined as discharge from the hospital and/or at least a two-point improvement from baseline on a predefined six-point scale, was 84 percent according to Kaplan-Meier analysis. Clinical improvement was less frequent among patients at least 70 years of age (HR vs < 50 years: 0.29 [95 percent CI 0.11, 0.74]). Compassionate use data have limitations due to the small size of the cohort, the relatively short duration of follow-up, potential missing data due to the nature of the program and lack of a randomized control group.

"Currently there is no proven treatment for COVID-19. We cannot draw definitive conclusions from these data, but the observations from this group of hospitalized patients who received remdesivir are hopeful," said Jonathan D. Grein, MD, Director of Hospital Epidemiology, Cedars-Sinai Medical Center, Los Angeles, and lead author of the journal article. "We look forward to the results of controlled clinical trials to potentially validate these findings."

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The overall mortality rate in this cohort was 13 percent (n=7/53). The mortality rate was higher in the subgroup of patients on invasive ventilation (18 percent, n=6/34), compared with patients on noninvasive oxygen support (5 percent, n=1/19). Factors associated with an increased risk of mortality included age greater than 70 years (HR vs < 70 years: 11.34 [95% CI 1.36, 94.17]) and higher baseline serum creatinine levels (HR per mg/dL: 1.91 [95% CI 1.22, 2.99]), indicating reduced kidney function.

Mild to moderate liver enzyme (ALT and/or AST) elevations (23 percent, n=12/53) were observed in this cohort. No new safety signals were detected during short-term remdesivir therapy.

Given the limitations of this data set and analysis, data from ongoing, randomized clinical studies of remdesivir are needed to provide a scientifically robust understanding of the clinical impact of remdesivir treatment.

"While the outcomes observed in this compassionate use analysis are encouraging, the data are limited," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "Gilead has multiple clinical trials underway for remdesivir with initial data expected in the coming weeks. Our goal is to add to the growing body of evidence as quickly as possible to more fully evaluate the potential of remdesivir and, if appropriate, support broader use of this investigational drug."

Gilead is conducting two Phase 3 clinical trials of remdesivir, the SIMPLE studies, in countries with high prevalence of COVID-19. Data from the SIMPLE study in patients with severe disease are expected this month, followed by data from the SIMPLE study in patients with moderate disease in May. In addition, Gilead is supporting multiple clinical trials led by other organizations, including two studies conducted in Hubei Province, China. Gilead has been informed that the study in China in patients with severe disease was terminated early due to low enrollment; the company awaits the publication of these data to enable an in-depth review of the results. The study in China in patients with mild-to-moderate disease is ongoing. A global study of remdesivir led by NIAID continues to enroll patients and data from this study are anticipated in May. Finally, additional studies of remdesivir and other investigational treatments for COVID-19, based on a master protocol by the World Health Organization, have also begun to enroll patients in countries around the world.

About the Compassionate Use Cohort Analysis

Since January 25, 2020, Gilead has been providing emergency access to remdesivir for qualifying patients with severe complications of COVID-19 who are unable to enroll in ongoing clinical trials. More than 1,800 patients have been treated with remdesivir through individual compassionate use protocols.

This cohort evaluated data from 53 patients in the United States, Europe, Canada and Japan who received at least one dose of remdesivir on or before March 7, 2020, through Gilead's compassionate use program. All patients were hospitalized with severe acute respiratory coronavirus 2 (SARS-CoV-2) infection and either an oxygen saturation of 94 percent or less, or a need for oxygen. The median duration of symptoms before initiation of remdesivir was 12 days. The majority of patients (75 percent) were men over the age of 60 years with comorbid conditions, including hypertension, diabetes, hyperlipidemia and asthma. Combined, all three of these factors have been associated with adverse outcomes of COVID-19.

The planned treatment was a 10-day course of remdesivir, consisting of a 200 mg loading dose administered intravenously on day 1, followed by 100 mg daily for the remaining nine treatment days. Of the 53 patients included in the analysis, 75 percent received the full 10-day course of remdesivir, 19 percent received 5-9 days of treatment, and 6 percent received fewer than 5 days of treatment. Follow-up continued through 28 days after initiation of remdesivir treatment. Four patients discontinued remdesivir prematurely, one due to worsening of pre-existing renal failure, one due to multiple organ failure and two due to elevated liver enzymes, including one patient with a maculopapular rash.

There were no prespecified endpoints for this program. As part of the analysis, rates of key clinical events were quantified, including change in oxygen support requirements, hospital discharge, reported adverse events leading to discontinuation of remdesivir treatment, and mortality. In addition, the analysis evaluated the proportion of patients with clinical improvement, defined as live discharge from the hospital and/or a clinical improvement of at least two points from baseline on a six-point scale reflecting hospitalization and oxygen support status, as recommended by the World Health Organization R&D Blueprint Group.

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. *In vitro* testing conducted by Gilead has demonstrated that remdesivir is active against the virus that causes COVID-19. The safety and efficacy of remdesivir to treat COVID-19 are being evaluated in multiple ongoing Phase 2 and 3 clinical trials. Initial clinical trial data are expected in April.

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

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. Remdesivir is an investigational agent that has not been licensed or approved anywhere globally, and it has not been demonstrated to be safe or effective for any use, including for the treatment of COVID-19. There is the possibility of unfavorable results from clinical trials involving remdesivir and the possibility that Gilead 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 or that FDA and other regulatory agencies may not approve remdesivir, and any marketing approvals, if granted, may have significant limitations on its us. 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.

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