

**CONTACTS:** Douglas Maffei, PhD, Investors (650) 522-2739

Sonia Choi, Media (650) 425-5483

#### **For Immediate Release**

### GILEAD ANNOUNCES RESULTS FROM PHASE 3 TRIAL OF INVESTIGATIONAL ANTIVIRAL REMDESIVIR IN PATIENTS WITH SEVERE COVID-19

#### -- Study Demonstrates Similar Efficacy with 5- and 10-Day Dosing Durations of Remdesivir --

**Foster City, Calif., April 29, 2020** – Gilead Sciences, Inc. (Nasdaq: GILD) today announced topline results from the open-label, Phase 3 SIMPLE trial evaluating 5-day and 10-day dosing durations of the investigational antiviral remdesivir in hospitalized patients with severe manifestations of COVID-19 disease. The study demonstrated that patients receiving a 10-day treatment course of remdesivir achieved similar improvement in clinical status compared with those taking a 5-day treatment course (Odds Ratio: 0.75 [95% CI 0.51 - 1.12] on Day 14). No new safety signals were identified with remdesivir across either treatment group. Gilead plans to submit the full data for publication in a peer-reviewed journal in the coming weeks.

"Unlike traditional drug development, we are attempting to evaluate an investigational agent alongside an evolving global pandemic. Multiple concurrent studies are helping inform whether remdesivir is a safe and effective treatment for COVID-19 and how to best utilize the drug," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "These study results complement data from the placebo-controlled study of remdesivir conducted by the National Institute for Allergy and Infectious Diseases and help to determine the optimal duration of treatment with remdesivir. The study demonstrates the potential for some patients to be treated with a 5-day regimen, which could significantly expand the number of patients who could be treated with our current supply of remdesivir. This is particularly important in the setting of a pandemic, to help hospitals and healthcare workers treat more patients in urgent need of care."

Remdesivir is not yet licensed or approved anywhere globally and has not yet been demonstrated to be safe or effective for the treatment of COVID-19. This study sought to determine whether a shorter, 5-day course of remdesivir would achieve similar efficacy results as the 10-day treatment regimen used in multiple ongoing studies of remdesivir. Secondary objectives included rates of adverse events and additional measures of clinical response in both treatment groups. Patients were required to have evidence of pneumonia and reduced oxygen levels that did not require mechanical ventilation at the time of study entry. Clinical improvement was defined as an improvement of two or more points from baseline on a predefined seven-point scale, ranging from hospital discharge to increasing levels of oxygen support to death. Patients achieved clinical recovery if they no longer required oxygen support and medical care or were discharged from the hospital.

In this study, the time to clinical improvement for 50 percent of patients was 10 days in the 5-day treatment group and 11 days in the 10-day treatment group. More than half of patients in both treatment groups were discharged from the hospital by Day 14 (5-day: 60.0%, n=120/200 vs.10-day: 52.3% n=103/197; p=0.14). At Day 14, 64.5 percent (n=129/200) of patients in the 5-day treatment group and 53.8 percent (n=106/197) of patients in the 10-day treatment group achieved clinical recovery.

Clinical outcomes varied by geography. Outside of Italy, the overall mortality rate at Day 14 was 7 percent (n=23/320) across both treatment groups, with 64 percent (n=205/320) of patients experiencing clinical improvement at Day 14 and 61 percent (n=196/320) of patients discharged from the hospital.

# **Impact of Earlier Treatment**

In an exploratory analysis, patients in the study who received remdesivir within 10 days of symptom onset had improved outcomes compared with those treated after more than 10 days of symptoms. Pooling data across treatment arms, by Day 14, 62 percent of patients treated early were able to be discharged from the hospital, compared with 49 percent of patients who were treated late.

"These data are encouraging as they indicate that patients who received a shorter, 5-day course of remdesivir experienced similar clinical improvement as patients who received a 10-day treatment course," said Aruna Subramanian, MD, Clinical Professor of Medicine, Chief, Immunocompromised Host Infectious Diseases, Stanford University School of Medicine, and one of the lead investigators of the study. "While additional data are still needed, these results help to bring a clearer understanding of how treatment with remdesivir may be optimized, if proven safe and effective."

Remdesivir was generally well-tolerated in both the 5-day and 10-day treatment groups. The most common adverse events occurring in more than 10 percent of patients in either group were nausea (5-day: 10.0%, n=20/200 vs. 10-day: 8.6%, n=17/197) and acute respiratory failure (5-day: 6.0%, n=12/200 vs. 10-day: 10.7%, n=21/197). Grade 3 or higher liver enzyme (ALT) elevations occurred in 7.3 percent (n=28/385) of patients, with 3.0 percent (n=12/397) of patients discontinuing remdesivir treatment due to elevated liver tests.

|  | 5-Day RDV | 10-Day RDV | Baseline adjusted    |
|--|-----------|------------|----------------------|
|  | n=200     | n=197      | p-value <sup>1</sup> |
| Clinical Efficacy Outcomes at Day 14           |           |            |                      |
| $\geq$ 2-point improvement in ordinal scale    | 129 (65)  | 107 (54)   | 0.16                 |
| Clinical recovery                              | 129 (65)  | 106 (54)   | 0.17                 |
| Discharge                                      | 120 (60)  | 103 (52)   | 0.44                 |
| Death  | 16 (8)    | 21 (11)    | 0.70                 |
| Safety   |           |            |                      |
| Any adverse event (AE)                         | 141 (71)  | 145 (74)   | 0.86                 |
| Grade $\geq$ 3 study drug-related AE           | 8 (4)     | 10 (5)     | 0.65                 |
| Study drug-related serious adverse event (SAE) | 3 (2)     | 4 (2)      | 0.73                 |
| AE leading to discontinuation                  | 9 (5)     | 20 (10)    | 0.07                 |

Key efficacy and safety results from the study are included in the table below.

<sup>1</sup>Adjusted for baseline clinical status

## **About the SIMPLE Trials**

Gilead initiated two randomized, open-label, multi-center Phase 3 clinical trials for remdesivir, the SIMPLE studies, in countries with high prevalence of COVID-19 infection.

The first SIMPLE trial is evaluating the safety and efficacy of 5-day and 10-day dosing regimens of remdesivir in hospitalized patients with severe manifestations of COVID-19. The initial phase of the study randomized 397 patients in a 1:1 ratio to receive remdesivir 200 mg on the first day, followed by remdesivir 100 mg each day until day 5 or 10, administered intravenously, in addition to standard of care. An expansion

phase of the study was recently added and will enroll an additional 5,600 patients, including patients on mechanical ventilation. The study is being conducted at 180 trial sites around the world, including sites in the United States, China, France, Germany, Hong Kong, Italy, Japan, Korea, the Netherlands, Singapore, Spain, Sweden, Switzerland, Taiwan and the United Kingdom.

A second SIMPLE trial is evaluating the safety and efficacy of 5-day and 10-day dosing durations of remdesivir administered intravenously in patients with moderate manifestations of COVID-19, compared with standard of care. The results from the first 600 patients of this study are expected at the end of May.

## 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 for the treatment of COVID-19 are being evaluated in multiple ongoing Phase 3 clinical trials.

### **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 ongoing and additional clinical trials involving remdesivir and the possibility that Gilead and other parties 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 use. 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 periodic reports filed with the U.S. Securities and Exchange Commission, including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K. 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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For more information about Gilead, please visit the company's website at <u>www.gilead.com</u>, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.