Gilead Sciences Statement on Data From Remdesivir Study in Patients With Severe COVID-19 in China

Foster City, Calif., April 23, 2020 – Gilead Sciences today issued the following statement from Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences:

“Today, information from the first clinical study evaluating the investigational antiviral remdesivir in patients with severe COVID-19 disease in China was prematurely posted on the World Health Organization website. This information has since been removed, as the study investigators did not provide permission for the publication of the results. Furthermore, we believe the post included inappropriate characterizations of the study. The study was terminated early due to low enrollment and, as a result, it was underpowered to enable statistically meaningful conclusions. As such, the study results are inconclusive, though trends in the data suggest a potential benefit for remdesivir, particularly among patients treated early in disease. We understand the available data have been submitted for peer-reviewed publication, which will provide more detailed information from this study in the near future.

The results of this trial in China, along with those of the compassionate use cohort of more critically ill patients published on April 10, add to a growing but still inconclusive body of evidence for remdesivir. Remdesivir is an unapproved investigational product, and the safety and efficacy of remdesivir for the treatment of COVID-19 are not yet known. There are multiple ongoing Phase 3 studies that are designed to provide the additional data needed to determine the potential for remdesivir as a treatment for COVID-19. These studies will help inform whom to treat, when to treat and how long to treat with remdesivir. The studies are either fully enrolled for the primary analysis or on track to fully enroll in the near future.

We expect to share results at the end of this month from our open-label study of remdesivir in patients with severe COVID-19 disease. This randomized clinical trial is fully enrolled and will compare treatment outcomes and safety following 5 or 10 days of remdesivir treatment. We expect data at the end of May from our open-label study in patients with moderate disease that is studying 5 or 10 days of remdesivir versus standard of care. We also anticipate data at the end of May from NIAID’s double-blind, placebo-controlled study of remdesivir in patients across a range of disease severity.

We appreciate the work done by the investigators in China and the continuing efforts of our colleagues and partners around the world to help inform our understanding of remdesivir’s potential as a treatment for this devastating illness. The incredible collaboration across the global health community to respond to COVID-19 has resulted in the rapid generation of data that move us toward understanding the natural history of COVID-19 infections and add to the understanding of the potential role of remdesivir in the treatment of this disease.”

Forward-Looking Statement
This statement 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 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 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.

# # #