GILEAD'S INVESTIGATIONAL ANTIVIRAL VEKLURY® (REMDESIVIR) RECEIVES U.S. FOOD AND DRUG ADMINISTRATION EMERGENCY USE AUTHORIZATION FOR THE TREATMENT OF PATIENTS WITH MODERATE COVID-19

- Expands Previous Authorization of Veklury to Treat Hospitalized Patients with COVID-19 Regardless of Oxygen Status -

Foster City, Calif., August 28, 2020 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced the U.S. Food and Drug Administration (FDA) expanded the Emergency Use Authorization (EUA) enabling use of the investigational antiviral Veklury® (remdesivir) to treat all hospitalized patients with COVID-19, in addition to the previous authorization for patients hospitalized with severe COVID-19. The expanded EUA is based on results from the Phase 3 SIMPLE trial evaluating Veklury in hospitalized patients with moderate COVID-19 pneumonia, as well as results from the National Institute of Allergy and Infectious Diseases (NIAID) ACTT-1 trial in hospitalized patients with a range of disease severity.

"With the growing understanding of the utility of Veklury to help improve outcomes for a range of patients with COVID-19, we welcome the FDA's decision to expand emergency use authorization," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "As we learn more about COVID-19 and we further establish the efficacy and safety profile of Veklury, we see benefit to making the drug available to patients at earlier stages of the disease. Today's action by the FDA enables physicians to consider a broader range of eligible patients to potentially receive Veklury."

Results from the Phase 3 SIMPLE study were published in the Journal of the American Medical Association (JAMA) on August 21, 2020 and confirm top-line results previously announced on June 1, 2020. The primary endpoint evaluated patients at Day 11 on a 7-point ordinal scale and found patients randomized to a 5-day course of Veklury plus standard of care were 65 percent more likely to have an improvement in clinical status compared with those randomized to standard of care alone (OR, 1.65; 95% confidence interval, 1.09-2.48; p=0.017). For patients in the 10-day Veklury group, the improvement in clinical status at Day 11 was not statistically different compared with the standard of care group (OR, 1.31; 95% confidence interval, 0.88-1.95; p=0.183).

"As our understanding of the spectrum of SARS-CoV-2 infection and the presentations and severity of COVID-19 continues to evolve, these results and the expanded EUA represent a new, important step that streamlines bedside prescribing of remdesivir without having to wait for patients to worsen clinically," said Francisco Marty, MD, an infectious diseases physician at Brigham and Women's Hospital, and associate professor of medicine at Harvard Medical School. "These study results show that patients with moderate COVID-19 disease may also benefit from a 5-day treatment course of remdesivir."

The data published in JAMA demonstrate that Veklury was generally well-tolerated in both the 5-day and 10-day treatment groups. The most commonly reported adverse events in the 5-day, 10-day, and standard of care groups, respectively, were nausea (10% vs 9% vs 3%), diarrhea (6% vs 5% vs 7%), hypokalemia (5% vs 7% vs 2%), and headache (5% vs 5% vs 3%). All-cause mortality at Day 28 was $\leq$ 2% in all treatment groups.

In the United States, Veklury is an investigational drug that has not been approved by the FDA, and the safety and efficacy of Veklury for the treatment of COVID-19 have not been established.

About the SIMPLE Trials

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

The first SIMPLE trial is evaluating the safety and efficacy of 5-day and 10-day dosing durations of Veklury administered intravenously 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 either a 5-day or a 10-day treatment course of Veklury in addition to standard of care. Moderate disease was defined in the study as any radiographic evidence of pulmonary infiltrates and oxygen saturation >94% on room air. An expansion phase of the study was added to enroll up to 5,600 additional patients, including those on mechanical ventilation.

The second SIMPLE trial is evaluating the safety and efficacy of 5-day and 10-day dosing durations of Veklury administered intravenously in hospitalized patients with moderate manifestations of COVID-19, compared with standard of care. The initial phase of the study randomized 600 patients in a 1:1:1 ratio to receive either a 5-day or a 10-day treatment course of Veklury in addition to standard of care, compared with standard of care alone. An expansion phase of the study was added to enroll up to 1,000 additional patients with moderate disease.

About Veklury (remdesivir)

Veklury is an investigational nucleotide analog with broad-spectrum antiviral activity both in vitro and in vivo in animal models against multiple emerging viral pathogens. Multiple ongoing international Phase 3 clinical trials are evaluating the safety and efficacy of Veklury for the treatment of SARS-CoV-2 infection, the virus that causes COVID-19, in different patient populations, formulations, and in combination with other therapies.