



VEKLURY® (REMDESIVIR) SIGNIFICANTLY REDUCED RISK OF HOSPITALIZATION IN HIGH-RISK PATIENTS WITH COVID-19

– Double-Blind Placebo-Controlled Study Evaluated the Efficacy of Early Use of Veklury IV in Non-Hospitalized Patients –

– Late-breaking Data to be Presented at IDWeek 2021 –

Foster City, Calif., September 22, 2021 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced positive results from a Phase 3 randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of a three-day course of Veklury® (remdesivir) for intravenous (IV) use for the treatment of COVID-19 in non-hospitalized patients at high risk for disease progression. This late-breaking data will be presented at the IDWeek 2021 virtual conference.

In an analysis of 562 participants randomly assigned in a 1:1 ratio to receive Veklury or placebo, Veklury demonstrated a statistically significant 87% reduction in risk for the composite primary endpoint of COVID-19 related hospitalization or all-cause death by Day 28 (0.7% [2/279]) compared with placebo (5.3% [15/283]) p=0.008.

Results also showed an 81% reduction in risk for the composite secondary endpoint of medical visits due to COVID-19 or all-cause death by Day 28 for participants treated with Veklury (1.6% [4/246]) compared with placebo (8.3% [21/252]) p=0.002. In the study, no deaths were observed in either arm by Day 28.

Enrollment for this trial was stopped prior to fulfilling enrollment targets in April 2021, reflecting the changing epidemiology and adoption of additional treatment options at the time; however, the study continued to collect data on enrolled participants and both investigators and participants remained blinded to their assignment of Veklury or placebo.

These results complement positive results from ACTT-1 and other studies in hospitalized patients in which Veklury helped patients recover significantly faster and reduced the likelihood of disease progression.

“Antiviral medications provide maximal benefit when used early in the disease course. Last summer, data from clinical trials demonstrated the benefit of remdesivir in patients hospitalized with COVID-19, even when not yet requiring oxygen. These latest data show remdesivir’s potential to help high-risk patients recover before they get sicker and stay out of the hospital altogether,” said Robert L. Gottlieb, MD, PhD, Cardiologist and Principal Investigator at Baylor University Medical Center and Baylor Scott & White Research Institute.

“We are seeing very high numbers of hospitalized patients as new COVID-19 infections surge, placing increased demands on already over-burdened healthcare systems. Remdesivir, also known as Veklury, is an effective antiviral for the treatment of hospitalized patients with COVID-19 and an essential tool to help reduce disease progression.”

The use of Veklury for the treatment of non-hospitalized patients with three days of dosing is investigational, and the safety and efficacy for this use and dosing duration have not been established or approved by any regulatory agency globally.

In the United States, Veklury is indicated for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. Veklury is

contraindicated in patients who are allergic to Veklury or any of its components; please see below for additional Important Safety Information for Veklury.

The safety profile was similar between Veklury and placebo in this trial, with the most common treatment emergent adverse events ($\geq 5\%$) in patients taking Veklury being nausea and headache. Of the 279 participants who received Veklury, no new safety signals were identified. One death was observed in the study at Day 59 (participant on placebo); no deaths occurred in either arm of the study by the Day 28 primary endpoint. Gilead is in the process of sharing the data with regulatory agencies.

“As the pandemic continues to evolve and new viral variants emerge, Veklury is playing a critical role as the antiviral standard of care for hospitalized patients, helping prevent disease progression and speed patients’ recovery,” said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. “As leaders in antiviral drug development, we welcome these findings and continue to invest in research of Veklury and novel oral antivirals to address the unmet need for effective and convenient therapies that can be administered at home.”

Gilead continues to study the efficacy and safety of Veklury in hospitalized patient populations with ongoing unmet needs, such as patients with renal impairment, children and pregnant women, as well as through the support of a number of externally sponsored trials. Gilead is also developing novel oral treatment options for non-hospitalized patients with COVID-19 and hopes to file investigational new drug applications (IND) with the Food and Drug Administration (FDA) by early next year.

About the IV Outpatient study (GS-US-540-9012)

Study GS-US-540-9012 ([PINETREE](#)) was a Phase 3, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of a three-day course of Veklury IV in reducing the rate of hospitalization or all-cause death among non-hospitalized COVID-19 patients at high risk for disease progression. The primary study endpoint was the composite of COVID-19 hospitalization or all-cause death by Day 28. The composite endpoint of medical visits due to COVID-19 or all-cause death by Day 28 was a secondary outcome measure.

The study was designed to enroll 1,264 participants, randomized in a double-blind fashion so that half of enrolled participants would receive Veklury and the other half would receive a matched placebo. Gilead decided to stop the study in April 2021, reflecting the evolution of the COVID-19 landscape and changing patient needs. At the time that enrollment was terminated, 584 participants were enrolled. The study remained blinded and participants already enrolled in the study were followed according to the protocol until the last patient visit occurred, and at that point the study was closed.

This trial was designed to evaluate the potential role of Veklury in helping patients diagnosed with COVID-19 who were considered high-risk for disease progression based on comorbidities and age but had not recently been hospitalized due to the infection. Common comorbidities in study participants included obesity, hypertension, and diabetes. A third of the participants were aged 60 or older. Participants in the study must have received a positive diagnosis within four days of initiating treatment and experienced symptoms for seven days or less.

About Veklury

Veklury (remdesivir) is a nucleotide analog invented by Gilead, building on more than a decade of the company’s antiviral research. Veklury is the antiviral standard of care for the treatment of hospitalized patients with COVID-19. At this time, more than half of patients hospitalized with COVID-19 in the United

States are treated with Veklury. Veklury is approved or authorized for temporary use in approximately 50 countries worldwide and generic remdesivir, manufactured by our voluntary licensing partners, is provided to 127 middle- and low-income countries. Veklury and generic remdesivir have been made available to more than seven million patients around the world. Veklury has broad-spectrum antiviral activity both *in vitro* and *in vivo* in animal models against multiple emerging viral pathogens, including Ebola, SARS, Marburg, and MERS.

Veklury is a nucleotide analog that directly inhibits viral replication of SARS-CoV-2 by targeting the viral RNA polymerase inside of the cell. On entering the body Veklury is transformed into the active metabolite remdesivir triphosphate, which is then incorporated into the viral RNA and stops replication of the virus within the host cell. No known variations have significantly altered the viral RNA polymerase. All known novel virus variants show mutations at different locations in the SARS-CoV-2 spike protein, which is on the outer surface of the virus and can cause decreased affinity of anti-SARS-CoV-2 antibodies.

Veklury's antiviral activity has been tested against isolates of variants of concern (VOCs), including Alpha, Beta, Gamma and Delta, and Epsilon, as well as one variant of interest (VOI) of SARS-CoV-2. These laboratory findings suggest that Veklury will continue to be active against the currently identified variations in the SARS-CoV-2 virus.