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

Sonia Choi, Media
(650) 425-5483

For Immediate Release

U.S. FOOD AND DRUG ADMINISTRATION APPROVES GILEAD'S ANTIVIRAL VEKLURY® (REMDESIVIR) FOR TREATMENT OF COVID-19

-- Veklury Is First and Only FDA-Approved Treatment for COVID-19 in the United States --

-- Veklury Shortened Time to Recovery By Five Days in Hospitalized COVID-19 Patients --

Foster City, Calif., October 22, 2020 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved the antiviral drug Veklury® (remdesivir) for the treatment of patients with COVID-19 requiring hospitalization. As an antiviral drug, Veklury works to stop replication of SARS-CoV-2, the virus that causes COVID-19. Previously authorized by the FDA for emergency use to treat COVID-19, Veklury is now the first and only approved COVID-19 treatment in the United States. The drug is now widely available in hospitals across the country, following early investments to rapidly expand manufacturing capacity to increase supply.

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 should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. 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.

This approval is based on three randomized controlled trials including the recently published, final results of the National Institute of Allergy and Infectious Diseases' (NIAID) double blind, placebo-controlled Phase 3 ACTT-1 trial, which showed that treatment with Veklury resulted in clinically meaningful improvements across multiple outcome assessments compared with placebo in hospitalized patients with COVID-19. Based on the strength of these data, Veklury has become a standard of care for the treatment of COVID-19 in hospitalized patients.

"The approval of Veklury marks an important milestone in efforts to help address the pandemic by offering an effective treatment that helps patients recover faster and, in turn, helps preserve scarce healthcare resources," said Barry Zingman, MD, Professor of Medicine at the Albert Einstein College of Medicine and Montefiore Medical Center, New York. "The availability of a rigorously tested treatment that can significantly speed recovery and offers other benefits such as lower rates of progression to mechanical ventilation, provides hospitalized patients and their families important hope and offers healthcare providers a critical tool as they care for patients in need."

"Since the beginning of the COVID-19 pandemic, Gilead has worked relentlessly to help find solutions to this global health crisis. It is incredible to be in the position today, less than one year since the earliest case reports of the disease now known as COVID-19, of having an FDA-approved treatment in the U.S. that is available for all appropriate patients in need," said Daniel O'Day, Chairman and Chief Executive Officer,

- more -

Gilead Sciences. "The speed and rigor with which Veklury has been developed and approved in the U.S. reflect the shared commitment of Gilead, government agencies and clinical trial investigators to advance well-tolerated, effective treatment options for the fight against COVID-19. We will continue to work at speed with the aim of enhancing patient outcomes with Veklury to ensure all patients with COVID-19 have the best chance at recovery."

In the randomized, double-blind, placebo-controlled ACTT-1 trial, Veklury significantly improved time to recovery as compared to placebo – by five days in the overall study population (10 vs. 15 days; rate ratio, 1.29; 95% CI, 1.12 to 1.49; $p<0.001$) and seven days in patients who required oxygen support at baseline (11 vs. 18 days; rate ratio, 1.31; 95% CI, 1.12 to 1.52). As a secondary endpoint, Veklury also reduced disease progression in patients needing oxygen, resulting in a significantly lower incidence of new mechanical ventilation or ECMO (13% vs. 23%; 95% CI, -15 to -4). In the overall patient population, there was a trend toward reduced mortality with Veklury compared with placebo at Day 29 (11.4% vs. 15.2%, HR 0.73; 95% CI, 0.52 to 1.03). Additional mortality data from a post-hoc analysis were published in the *New England Journal of Medicine* on October 8, 2020.

The ACTT-1 trial results are complemented by results of two Phase 3 open-label trials of Veklury conducted in adult patients with severe and moderate COVID-19. The SIMPLE-Severe trial, conducted in hospitalized patients who required supplemental oxygen and who were not mechanically ventilated, found that a five-day or a 10-day treatment course of Veklury achieved similar clinical outcomes (odds ratio 0.75; 95% CI, 0.51 to 1.12). The SIMPLE-Moderate trial, conducted in hospitalized patients who did not require supplemental oxygen, showed statistically improved clinical outcomes with a five-day treatment course of Veklury compared with standard of care (odds ratio 1.65; 95% CI, 1.09 to 2.48; $p=0.017$). The odds of improvement in clinical status with the 10-day treatment course of Veklury versus standard of care were also favorable, trending toward but not reaching statistical significance (odds ratio 1.31; 95% CI, 0.88 to 1.95).

The incidence of adverse events associated with Veklury was similar to placebo in the ACTT-1 trial. Rates of serious adverse events (SAEs) were numerically higher in the placebo group compared with the Veklury group. Treatment discontinuation, all-cause grade 3 and 4 adverse events (AEs) and laboratory abnormalities were similar across groups. In the SIMPLE-Severe trial, the most common adverse reactions occurring in at least 5% of subjects in either the Veklury 5-day or 10-day group, respectively, were nausea (5% vs 3%), AST increased (3% vs 6%), and ALT increased (2% vs 7%). In the SIMPLE-Moderate trial, the most common adverse reaction occurring in at least 5% of subjects in the Veklury groups was nausea (7% in the 5-day group, 4% in the 10-day group).

In parallel with the FDA approval of Veklury, the FDA also issued a new Emergency Use Authorization (EUA) for the use of Veklury to treat hospitalized pediatric patients under 12 years of age weighing at least 3.5 kg or hospitalized pediatric patients weighing 3.5 kg to less than 40 kg with suspected or laboratory confirmed COVID-19 for whom use of an intravenous (IV) agent is clinically appropriate. This authorization is temporary and may be revoked, and does not take the place of the formal submission, review and approval process for the use of Veklury in this patient population. The use of Veklury in pediatric patients under 12 years of age or weighing less than 40 kg has not been approved by FDA, and the safety and efficacy of Veklury for this use has not been established. For information about the authorized use of Veklury in pediatric patients and mandatory requirements of the EUA in the U.S., please review the Fact Sheets and FDA Letter of Authorization available at www.gilead.com/remdesivir.

About the ACTT-1 Trial
The global, randomized, double-blind, placebo-controlled, Phase 3 clinical trial ACTT-1 (NTC04280705) sponsored by the National Institute of Allergy and Infectious Diseases (NIAID) evaluated the efficacy and safety of a 10-day treatment course of Veklury versus placebo in 1,063 hospitalized adult patients with confirmed SARS-CoV-2 infection and mild, moderate or severe COVID-19 who also were receiving treatment with standard of care.

The primary outcome measure of ACTT-1 was time to recovery within 29 days after randomization. Recovery was defined as discharged from the hospital without limitations on activities, discharged from the hospital with limitations on activities and/or requiring home oxygen, or hospitalized but not requiring supplemental oxygen and no longer requiring ongoing medical care.

About the SIMPLE Trials
Gilead's two open-label Phase 3 trials of Veklury were conducted in countries with a high prevalence of COVID-19 infections and included U.S. trial sites that serve diverse communities.

The SIMPLE-Severe trial (NCT04292899) was a randomized, open-label multi-center study that evaluated the efficacy and safety of five-day and 10-day dosing durations of Veklury plus standard of care in 397 hospitalized adult patients with severe COVID-19. Severe COVID-19 was defined as patients with confirmed SARS-CoV-2 infection, an SpO2 of ≤94% on room air, and radiological evidence of pneumonia. The primary endpoint was clinical status on Day 14 assessed on a 7-point ordinal scale. Treatment with Veklury was stopped in subjects who were discharged from the hospital prior to completion of their protocol-defined duration of treatment.

The SIMPLE-Moderate trial (NCT04292730) was a randomized, controlled, open-label multi-center study that evaluated the efficacy and safety of five-day and 10-day dosing durations of Veklury plus standard of care compared with standard of care alone in 600 hospitalized adult patients with moderate COVID-19. Moderate COVID-19 was defined as confirmed SARS-CoV-2 infection, SpO2 >94% and radiological evidence of pneumonia. The primary endpoint was clinical status on Day 11 assessed on a 7-point ordinal scale.

About Veklury
Veklury (remdesivir) is a nucleotide analog invented by Gilead, building on more than a decade of the company's antiviral research. Veklury has broad-spectrum antiviral activity both in vitro and in vivo in animal models against multiple emerging viral pathogens, including Ebola, SARS, Marburg, MERS and SARS-CoV-2, the virus that causes COVID-19.

Veklury has been approved or authorized for temporary use as a COVID-19 treatment in approximately 50 countries worldwide. In our continuing commitment to develop effective treatments for COVID-19, multiple ongoing international Phase 3 clinical trials are evaluating the safety and efficacy of Veklury for the treatment of COVID-19, in different patient populations, formulations, and in combination with other therapies.

As announced on October 1, 2020, Gilead is now meeting real-time demand for Veklury in the United States and anticipates meeting global demand for Veklury in October, even in the event of potential future surges of COVID-19.

- more -

U.S. Important Safety Information for Veklury

Contraindication

- VEKLURY is contraindicated in patients with a history of clinically significant hypersensitivity reactions to VEKLURY or any of its components.

Warnings and precautions

- Hypersensitivity, including infusion-related and anaphylactic reactions: Hypersensitivity, including infusion-related and anaphylactic reactions, has been observed during and following administration of VEKLURY. Monitor patients under close medical supervision for hypersensitivity reactions during and following administration of VEKLURY. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time ≤120 minutes) can potentially prevent these reactions. If a severe infusion-related hypersensitivity reaction occurs, immediately discontinue VEKLURY and initiate appropriate treatment (see Contraindications).
- Increased risk of transaminase elevations: Transaminase elevations have been observed in healthy volunteers and in patients with COVID-19 who received VEKLURY; these elevations have also been reported as a clinical feature of COVID-19. Perform hepatic laboratory testing in all patients (see Dosage and administration). Consider discontinuing VEKLURY if ALT levels increase to >10x ULN. Discontinue VEKLURY if ALT elevation is accompanied by signs or symptoms of liver inflammation.
- Risk of reduced antiviral activity when coadministered with chloroquine or hydroxychloroquine: Coadministration of VEKLURY with chloroquine phosphate or hydroxychloroquine sulfate is not recommended due to antagonism observed in cell culture, which may lead to a decrease in antiviral activity of VEKLURY

Adverse reactions

- The most common adverse reaction (≥5% all grades) was nausea.
- The most common lab abnormalities (≥5% all grades) were increases in ALT and AST.

Drug interactions

- Drug interaction trials of VEKLURY and other concomitant medications have not been conducted in humans.

Dosage and administration

- Dosage: For adults and pediatric patients ≥12 years old and weighing ≥40 kg: 200 mg on Day 1, followed by once-daily maintenance doses of 100 mg from Day 2 administered only via intravenous infusion over 30 to 120 minutes.
- Treatment duration: For patients not requiring invasive mechanical ventilation and/or extracorporeal membrane oxygenation (ECMO): 5 days; may be extended up to 5 additional days (10 days total) if clinical improvement is not observed. For patients requiring invasive mechanical ventilation and/or ECMO: 10 days.
- Testing prior to and during treatment: Perform eGFR, hepatic laboratory, and prothrombin time testing prior to initiating VEKLURY and during use as clinically appropriate.
- Renal impairment: VEKLURY is not recommended in individuals with eGFR <30 mL/min.
- Dose preparation and administration: See full Prescribing Information.

Pregnancy and lactation

- Pregnancy: There are insufficient human data on the use of VEKLURY during pregnancy. Pregnant women hospitalized with COVID-19 are at risk for serious morbidity and mortality. VEKLURY should be used during pregnancy only if the potential benefit justifies the potential risk for the mother and the fetus.
- Lactation: It is not known whether VEKLURY can pass into breast milk. Breastfeeding individuals with COVID-19 should follow practices according to clinical guidelines to avoid exposing the infant to COVID-19.

U.S. Indication for Veklury

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 should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.

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: https://www.gilead.com/purpose/advancing-global-health/covid-19.

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, including the risk that Veklury may not be successfully commercialized or that Gilead may be unable to effectively manage the global supply and distribution of Veklury. There is also the possibility of unfavorable results from ongoing and additional clinical trials involving Veklury 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. 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, 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.

# # #

U.S. full Prescribing Information for Veklury is available at www.gilead.com.

For information on the emergency use of Veklury in pediatric patients under 12 years of age or weighing less than 40 kg, please see the U.S. Emergency Use Authorization Fact Sheets available at www.gilead.com/remdesivir.

For more information about Gilead, please visit the company's website at www.gilead.com, follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000.