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FOR IMMEDIATE RELEASE

VEKLURY® (REMDESIVIR) IS FIRST AND ONLY APPROVED TREATMENT FOR PEDIATRIC PATIENTS UNDER 12 YEARS OF AGE WITH COVID-19

-- Approval is Supported by Phase 2/3 Data Demonstrating the Safety and Tolerability Profile and Clinical Improvement Outcome in Hospitalized Pediatric Patients Treated with Veklury --

Foster City, Calif., April 25, 2022 – Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application (sNDA) for Veklury® (remdesivir) for the treatment of pediatric patients who are older than 28 days, weighing at least 3 kg, and are either hospitalized with COVID-19 or have mild-to-moderate COVID-19 and are considered high risk for progression to severe COVID-19, including hospitalization or death. This approval follows the recent sNDA approval for Veklury for the treatment of non-hospitalized adult and adolescent patients who are at high risk of progression to severe COVID-19.

Under the expanded indication, a three-day Veklury treatment regimen is recommended to help prevent hospitalization in non-hospitalized COVID-19 pediatric patients who are at high risk for COVID-19 disease progression. For hospitalized pediatric patients who do not require invasive mechanical ventilation and/or ECMO, a 5-day treatment course is recommended. 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 means that remdesivir can potentially provide meaningful clinical improvement, by reducing disease progression and helping children recover from COVID-19 more quickly," said Amina Ahmed, MD, Atrium Health-Levine Children's Hospital in Charlotte, North Carolina in the United States. "We need proven antiviral treatment options, like remdesivir, that can help treat some of the most vulnerable in our society: children."

This approval was supported by results from the CARAVAN Phase 2/3 single arm, open-label study, which demonstrated that Veklury was generally well-tolerated among pediatric patients hospitalized with COVID-19 with a high proportion of participants showing clinical improvement and recovery, as well as data from trials in adults. Of the 53 pediatric patients enrolled in the CARAVAN study, no new safety signals were apparent for patients treated with Veklury. Overall, 75% and 85% showed clinical improvement (≥2 point increase on the ordinal scale) at Day 10 and last assessment, respectively, while 60% and 83% were discharged by Day 10 and Day 30, respectively. In the study 38 patients (72%) experienced adverse events (AEs), with 11 patients (21%) experiencing serious adverse events (SAEs) that were determined not to be study-drug related, including three participant deaths, which were consistent with the patients' underlying medical conditions prior to study entry or with COVID-19 disease during hospitalization. These data were presented at the 29th Conference on Retroviruses and Opportunistic Infections (virtual CROI 2022).

"The expanded indication for Veklury for the treatment of children is a testament to the safety, tolerability and efficacy profile of this therapy, which has remained the foundational antiviral for COVID-19 treatment," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "Effective and tolerable options for children require our best science and a dedicated focus. With the recent opening of our Gilead Pediatric Center of Excellence in Dublin, which is responsible for coordinating pediatric clinical trials for treatments for HIV, hepatitis B and COVID-19, we will continue our research to help address unmet treatment needs for children."

In the United States, Veklury is indicated for the treatment of COVID-19 in adults and pediatric patients (28 days and older and weighing at least 3 kg) who are either hospitalized or not hospitalized and are at high risk for progression to severe COVID-19, including hospitalization or death. 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.

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 a foundation for the treatment of hospitalized patients with COVID-19 and is a recommended treatment for reducing disease progression in non-hospitalized patients at high risk of disease progression. Veklury has an established safety profile and minimal drug interactions in diverse populations. At this time, more than half of patients hospitalized with COVID-19 in the United States are treated with Veklury. It can help reduce disease progression across a spectrum of disease severity and enable patients to recover faster, freeing up limited hospital resources and saving healthcare systems money.

Veklury was approved by the FDA in October 2020, 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. In January 2022, the FDA approved a sNDA to expand the indication to non-hospitalized adult and adolescent patients who are at high risk of progression to severe COVID-19, including hospitalization or death. This allows for Veklury to be administered in qualified outpatient settings that can administer daily intravenous (IV) infusions over three consecutive days. In April 2022, Veklury was approved by the FDA for the treatment of pediatric patients over 28 days old and weighing at least 3 kg who are hospitalized or not hospitalized and at high risk of progression to severe COVID-19, including hospitalization or death. 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.

Veklury continues to demonstrate durable activity against SARS-CoV2 as it evolves. Veklury is a nucleotide analog that directly inhibits viral replication inside of the cell by targeting the SARS-CoV-2 viral RNA polymerase. *In vitro* laboratory testing in multiple independent studies show that Veklury continues to demonstrate durable activity against SARS-CoV2 as it evolves, including the Omicron variant and its subvariants BA.1 and BA.2. As new SARS-CoV-2 variants of concern emerge around the world, Gilead continuously evaluates the effectiveness of Veklury against viral variants.

Veklury is approved or authorized for temporary use in approximately 50 countries worldwide. To date, Veklury and generic remdesivir have been made available to more than 11 million patients around the world, including more than 7 million people in 127 middle- and low-income countries through Gilead's voluntary licensing program. These licenses currently remain royalty-free, reflecting Gilead's existing commitment to enabling broad patient access to remdesivir.

U.S. Indication for Veklury

Veklury® (remdesivir 100 mg for injection) is indicated for the treatment of COVID-19 in adults and pediatric patients (≥28 days old and weighing ≥3 kg) with positive results of SARS-CoV-2 viral testing, who are:

- Hospitalized, or
- Not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

For more information, please see the U.S. full Prescribing Information available at www.gilead.com.

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; most occurred within one hour. Monitor patients during infusion and observe for at least one hour after infusion is complete for signs and symptoms of hypersensitivity as clinically appropriate. Symptoms may include hypotension, hypertension, tachycardia, bradycardia, hypoxia, fever, dyspnea, wheezing, angioedema, rash, nausea, diaphoresis, and shivering. Slower infusion rates (maximum infusion time up to 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 based on data from cell culture experiments, demonstrating potential antagonism, 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 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. For pediatric patients ≥28 days and weighing ≥3 kg: 5 mg/kg on Day 1, followed by once-daily maintenance doses of 2.5 mg/kg from Day 2, administered only via intravenous infusion.

- Treatment duration:
    - For hospitalized patients requiring invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days. Veklury should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
    - For hospitalized patients not requiring invasive mechanical ventilation and/or ECMO, the recommended treatment duration is 5 days. If a patient does not demonstrate clinical improvement, treatment may be extended for up to 5 additional days for a total treatment duration of up to 10 days.
    - For non-hospitalized patients diagnosed with mild-to-moderate COVID-19 who are at high risk for progression to severe COVID-19, including hospitalization or death, the recommended total treatment duration is 3 days. Veklury should be initiated as soon as possible after diagnosis of symptomatic COVID-19 and within 7 days of symptom onset.
- 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:

- There are two different formulations of Veklury: Veklury for injection (supplied as 100 mg lyophilized powder in vial) and Veklury injection (supplied as 100 mg/20 mL [5 mg/mL] solution in vial). The only approved dosage form for pediatric patients weighing 3 kg to ≤40 kg is the lyophilized powder formulation; See full Prescribing Information.
- Administration should take place only under conditions where management of severe hypersensitivity reactions, such as anaphylaxis, is possible

Pregnancy and lactation

- Pregnancy: A pregnancy registry has been established. There are insufficient human data on the use of Veklury during pregnancy. COVID-19 is associated with adverse maternal and fetal outcomes, including preeclampsia, eclampsia, preterm birth, premature rupture of membranes, venous thromboembolic disease and fetal death.
- 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.

About Gilead Sciences

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

Forward-Looking Statements

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 Gilead's ability to effectively manage the supply and distribution of Veklury, including for the use of Veklury in pediatric patients in the United States who are hospitalized with or at high risk of hospitalization for COVID-19; the possibility of unfavorable results from ongoing or additional clinical trials, including those involving Veklury; Gilead's ability to initiate, progress or complete clinical trials within currently anticipated timelines or at all, including those involving Veklury;and any assumptions underlying any of the foregoing. These and other risks, uncertainties and factors are described in detail in Gilead's Annual

Report on Form 10-K for the year ended December 31, 2021, as filed with the U.S. Securities and Exchange Commission. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. The reader is cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties, and is cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation and disclaims any intent to update any such forward-looking statements.

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

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