



GILEAD STATEMENT ON WHO RECOMMENDATION OF VEKLURY® (REMDESIVIR) AND ACCELERATION OF PREQUALIFICATION SUBMISSION

Foster City, Calif., April 21, 2022 – Gilead today announced updates to the World Health Organization’s (WHO) [Therapeutics and COVID-19: living guideline](#), which now conditionally recommends Veklury® (remdesivir) for use in the treatment of patients with non-severe COVID-19 at the highest risk of hospitalization. The revised recommendation is based on evidence from our Phase 3 double-blind, placebo-controlled trial (PINETREE) demonstrating that a three-day course of Veklury treatment significantly reduced the risk of hospitalization for non-hospitalized patients at high risk of disease progression.

We welcome today’s updated guideline as affirmation of the importance of early treatment of COVID-19 with an antiviral. We will continue to share data from clinical trials and real-world evidence supporting the use of Veklury across a spectrum of disease severity with the WHO for future updates of its living guidance. The updated WHO guideline recognizes the important role of Veklury in helping people at high risk of COVID-19 disease progression but do not currently reflect the broad body of evidence supporting Veklury’s effectiveness across a broad spectrum of disease severity, as do several other global treatment guidelines. We anticipate the WHO will continue to consider robust evidence from multiple randomized, controlled trials, including ACTT-1 and independent meta-analysis, which demonstrate the efficacy of Veklury in later-stage COVID-19 disease, and update their recommendation for patients with severe or critical illness.

Veklury is playing a critical role in the pandemic by helping to prevent disease progression and enabling patients to recover faster. Veklury is recommended worldwide in both mild-to-moderate and severe COVID-19 disease by several key guidelines in more than 40 countries, including the National Institutes of Health and Infectious Diseases Society of America, National Institute for Health and Care Excellence, European Society of Clinical Microbiology and Infectious Diseases, and the Ministry of Health, Labour and Welfare of Japan.

The current conditional recommendation for Veklury in patients with non-severe illness at highest risk of hospitalization replaces a previous conditional recommendation against treatment

with Veklury in all patients with COVID-19 regardless of disease severity. We anticipate the recommendation for patients with severe or critical illness will be updated as the WHO reviews new evidence.

Earlier this month, Gilead accelerated its application for remdesivir prequalification, following a formal invitation and Expression of Interest (EOI) from the WHO. Prequalification of remdesivir may help improve access in countries where it has not yet been available. Veklury and generic remdesivir have been made available to 11 million patients around the world, including 7 million people in 127 low- and lower-middle-income countries through Gilead's voluntary licensing program. These licenses remain royalty-free, reflecting Gilead's existing commitment to enabling global equity with broad patient access to remdesivir.

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 broad spectrum of disease severity and enable patients to recover faster, freeing up limited hospital resources and saving healthcare systems money.

Results from a [recent independent meta-analysis](#) of eight randomized controlled trials, found that Veklury was associated with a statistically significant 17% reduced risk of mortality for patients who required oxygen but were not yet critically ill (e.g., not on mechanical ventilation). This finding complements results from ACTT-1 that found no reduction in mortality in the overall patient population, but which demonstrated a mortality reduction in Veklury-treated patients on low flow oxygen at baseline in a post-hoc subgroup analysis.

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 supplemental NDA 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. Veklury also has an Emergency Use Authorization (EUA) for non-hospitalized pediatric patients weighing at least 3.5 kg who are younger than 12 years of age or weighing less than 40 kg who are at high risk of disease progression, in addition to those with 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.

Veklury continues to demonstrate durable activity against SARS-CoV-2 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-CoV-2 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.

U.S. Indication for Veklury

Veklury[®] (remdesivir 100 mg for injection) is indicated for the treatment of COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) with positive results of direct 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.

Veklury should only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion or hypersensitivity reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. Veklury must be administered by intravenous infusion. Veklury is contraindicated in patients who are allergic to Veklury or any of its components. 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 $>10\times$ 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 ($\geq 5\%$ all grades) was nausea.
- The most common lab abnormalities ($\geq 5\%$ 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. Veklury should be initiated as soon as possible after diagnosis of symptomatic COVID-19.
- Treatment duration:
 - For hospitalized patients requiring invasive mechanical ventilation and/or ECMO, the recommended total treatment duration is 10 days.
 - 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.
- 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: 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 communication 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 possibility of unfavorable results from ongoing or additional clinical trials and other studies involving Veklury (remdesivir); Gilead's ability to receive additional regulatory approvals or favorable updates to the WHO guideline and other global treatment guidelines for Veklury in a timely manner or at all; 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.

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

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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.