



**VEKLURY® (REMDESIVIR) RETAINS ANTIVIRAL ACTIVITY AGAINST OMICRON, DELTA AND OTHER EMERGENT SARS-COV-2 VARIANTS IN MULTIPLE *IN VITRO* STUDIES**

*– Data Supports the Continued Use of Veklury for Treatment of COVID-19 For Current SARS-CoV-2 Variants –*

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today released data demonstrating the *in vitro* activity of Veklury® (remdesivir) against ten SARS-CoV-2 variants, including Omicron. Results of Gilead studies are consistent with other *in vitro* studies independently conducted by researchers from institutions in other countries, including Belgium, Czech Republic, Germany, Poland, and the United States, which confirmed Veklury's antiviral activity against multiple previously identified variants of SARS-CoV-2, including Alpha, Beta, Gamma, Delta and Omicron.

The study analyzed *in vitro* antiviral activity by two methods to understand the susceptibility of ten major SARS-CoV-2 variants to Veklury. The study results showed similar activity of Veklury against the variants and an early ancestral A lineage isolate detected in Seattle, WA (WA1 strain). Specifically, Delta and Omicron variants both remained fully susceptible to Veklury, and these laboratory results demonstrate that Veklury has remained active against all major variants isolated over the past two years.

Veklury directly inhibits viral replication inside host cells by targeting the SARS-CoV-2 RNA-dependent RNA polymerase. On entering the body, Veklury is transformed into the active triphosphate metabolite, which is then incorporated into the viral RNA and stops replication of the virus within the infected cells. The study analyzed nearly 6 million publicly available variant isolate sequences and confirmed that the nsp12 protein, the RNA polymerase target of Veklury, is highly conserved across all variants. Further characterization confirmed that none of the few identified nsp12 mutations prevalent in some of the SARS-CoV-2 variants affects the virus susceptibility to Veklury.

“These results provide evidence of the consistent and durable antiviral activity of remdesivir across known variants that have emerged throughout the pandemic, including Omicron and support its continued use for the treatment of COVID-19 for current SARS-CoV-2 variants,” said Tomas Cihlar, Senior Vice President of Virology Research, Gilead Sciences. “Now with a new version of Omicron (BA.2 subvariant) increasing in circulation around the world, these latest data also suggest that remdesivir will retain antiviral activity against this new subvariant because the viral RNA polymerase that remdesivir targets does not contain any additional unique mutations. Gilead continuously evaluates the activity of Veklury against viral variants.”

The results of this study have been submitted for publication in a peer-reviewed journal and have been uploaded as preprint at BioRxiv available [here](#).

### **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 and is a recommended treatment for reducing disease progression in non-hospitalized patients at high risk of disease progression. 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 U.S. Food and Drug Administration (FDA) on October 22, 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. On January 21, 2022, the FDA approved a supplemental new drug application (sNDA) for Veklury to expand the indication to the treatment of non-hospitalized adult and adolescent patients who are at high risk of progression to severe COVID-19, including hospitalization or death. The expanded indication allows for Veklury to be administered in qualified outpatient settings that can administer daily intravenous (IV) infusions over three consecutive days. 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 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 10 million patients around the world, including nearly 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 (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](http://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  $\geq 12$  years old and weighing  $\geq 40$  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 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 possibility of unfavorable results from ongoing or additional clinical trials involving Veklury and Gilead's ability to effectively manage the supply and distribution of

Veklury. These and other risks, uncertainties and factors are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 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 involves 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](http://www.gilead.com).*

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

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Jacquie Ross, Investors  
(408) 656-8793

Nicole Rodriguez, Media  
(650) 235-2493  
Source: Gilead Sciences, Inc.