



Gilead Submits New Drug Application to U.S. Food and Drug Administration for Veklury® (Remdesivir) for the Treatment of COVID-19

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-- Veklury is Currently Available in the U.S. for the Treatment of Severe COVID-19 Under an Emergency Use Authorization --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Aug. 10, 2020-- Gilead Sciences, Inc. (Nasdaq: GILD) announced today that it has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for Veklury® (remdesivir), an investigational antiviral for the treatment of patients with COVID-19. Veklury is currently available in the U.S. under an Emergency Use Authorization for the treatment of hospitalized patients with severe COVID-19. The filing is the final tier of the rolling NDA submission that was initiated on April 8, 2020.

The filing is supported by data from two randomized, open-label, multi-center Phase 3 clinical studies of Veklury conducted by Gilead and the Phase 3 randomized, placebo-controlled study of Veklury conducted by the National Institute of Allergy and Infectious Diseases (NIAID). These studies demonstrated that treatment with Veklury led to faster time to recovery compared with placebo and that a 5-day or 10-day treatment duration led to similar clinical improvement. Across studies, Veklury was generally well-tolerated in both the 5-day and 10-day treatment groups, with no new safety signals identified.

"Since the beginning of the pandemic, Gilead has worked with urgency to establish the efficacy and safety profile of Veklury, and we now have a robust data set supporting the evaluation of use of the drug across a range of hospitalized COVID-19 patient populations," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "Today's filing is an important milestone as we continue to partner with the U.S. government and healthcare authorities around the globe to address the treatment needs of patients with COVID-19."

Veklury has been approved by multiple regulatory authorities around the world, including in the European Union and Japan. In countries where Veklury has not been approved, including the United States, Veklury is an investigational drug and the safety and efficacy of remdesivir have not been established. Please see below for additional important warnings and information about the authorized use of Veklury in the United States.

About Veklury

Veklury (remdesivir) is an investigational nucleotide analog with broad-spectrum antiviral activity both in vitro and in vivo in animal models against multiple emerging viral pathogens. Multiple ongoing international Phase 3 clinical trials are evaluating the safety and efficacy of Veklury for the treatment of SARS-CoV-2 infection, the virus that causes COVID-19, in different patient populations, formulations, and in combination with other therapies.

Important Information about Veklury in the United States

In the United States, Veklury (remdesivir) is authorized for use under an Emergency Use Authorization (EUA) only for the treatment of patients with suspected or laboratory-confirmed SARS-CoV-2 infection and severe COVID-19. Severe disease is defined as patients with an oxygen saturation (SpO₂) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO). Veklury must be administered via intravenous (IV) infusion and is supplied two ways: Veklury (remdesivir) for injection, 100 mg, lyophilized powder, or Veklury (remdesivir) injection, 100 mg/20 mL (5 mg/mL), concentrated solution.

Veklury is an investigational drug that has not been approved by the FDA for any use, and the safety and efficacy of Veklury for the treatment of COVID-19 have not been established. This authorization is temporary and may be revoked, and does not take the place of the formal new drug application submission, review and approval process. For information about the authorized use of Veklury 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.

There are limited clinical data available for Veklury. Serious and unexpected adverse events may occur that have not been previously reported with Veklury use. Hypersensitivity reactions, including infusion-related and anaphylactic reactions, have been observed during and following administration of Veklury. The use of Veklury is contraindicated in patients with known hypersensitivity to remdesivir. Transaminase elevations have been observed in healthy volunteers and patients with COVID-19 in clinical trials who received Veklury. Patients should have appropriate clinical and laboratory monitoring to aid in early detection of any potential adverse events. Monitor renal and hepatic function prior to initiating and daily during therapy with Veklury; additionally monitor serum chemistries and hematology daily during therapy. Do not initiate Veklury in patients with ALT ≥5x ULN or with an eGFR <30 mL/min. The decision to continue or discontinue Veklury therapy after development of an adverse event should be made based on the clinical risk/benefit assessment for the individual patient.

Due to a risk of reduced antiviral activity, coadministration of Veklury and chloroquine phosphate or hydroxychloroquine sulfate is not recommended.

Healthcare providers and/or their designee are responsible for mandatory FDA MedWatch reporting of all medication errors and serious adverse events or deaths occurring during Veklury treatment and considered to be potentially attributable to Veklury. These events must be reported within 7 calendar days from the onset of the event. MedWatch adverse event reports can be submitted to FDA online at www.fda.gov/medwatch or by calling 1-800-FDA-1088.

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. Veklury (remdesivir) is an investigational drug that has not been approved by the FDA for any use, and it is not yet known if Veklury is safe or effective for the treatment of COVID-19. There is 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. Further, it is possible that Gilead may make a strategic decision to discontinue development of Veklury or that FDA and other regulatory agencies may not approve Veklury, and any marketing approvals, if granted, may have significant limitations on its use. As a result, Veklury may never be successfully commercialized. In addition, Gilead may be unable to sufficiently scale up the production of Veklury in the currently anticipated timelines, and Gilead may be unable to meet future supply needs. 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.

For more information about the emergency use of Veklury (remdesivir) in the United States, please see the Emergency Use Authorization Fact Sheets available at www.gilead.com/remdesivir.

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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.

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