



European Commission Grants Conditional Marketing Authorization for Gilead's Veklury® (remdesivir) for the Treatment of COVID-19

July 3, 2020

-- Veklury is the First Approved Treatment Option for COVID-19 in the European Union --

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jul. 3, 2020-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the European Commission has granted conditional marketing authorization for Veklury® (remdesivir) as a treatment for SARS-CoV-2 infection, the virus that causes COVID-19. The conditional marketing authorization was granted in the interest of public health due to the COVID-19 pandemic and was based on a rolling review of supporting data that began in April 2020.

Under this authorization, Veklury is indicated for the treatment of COVID-19 in adults and adolescents (aged 12 years and older and weighing at least 40 kg), with pneumonia requiring supplemental oxygen.

"We appreciate the European Medicines Agency's rapid review of remdesivir in recognition of the unprecedented nature of this pandemic," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "This conditional marketing authorization is an important step forward as we work together to address the treatment needs of patients across Europe."

Veklury has been studied in hospitalized COVID-19 patients spanning a range of disease severity. The conditional marketing authorization for Veklury is supported by the U.S. National Institute of Allergy and Infectious Diseases' global Phase 3 trial of remdesivir. A conditional marketing authorization in Europe is initially valid for one year but can be extended or converted into an unconditional marketing authorization after the submission and assessment of additional confirmatory data.

Ongoing clinical trials continue to evaluate the safety and efficacy of remdesivir, including studies of remdesivir in combination with anti-inflammatory medicines and in special populations including pediatric patients. Research is also being conducted on new, investigational formulations of remdesivir that may enable studies of remdesivir in earlier stages of disease.

About Veklury

Veklury (remdesivir) is a 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 remdesivir for the treatment of SARS-CoV-2, the virus that causes COVID-19. In recognition of the current public health emergency and based on available clinical data, remdesivir has been approved as a treatment for patients with severe COVID-19 in Japan, Taiwan, India, Singapore, the United Arab Emirates and the European Union. Outside of these regions, remdesivir is an investigational, unapproved drug.

Important Information about Remdesivir in the United States

In the United States, remdesivir (GS-5734™) 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). Remdesivir is authorized for adult or pediatric patients who are admitted to a hospital and for whom use of an IV agent is clinically appropriate, as remdesivir must be administered intravenously.

Remdesivir is an investigational drug that has not been approved by the FDA for any use, and the safety and efficacy of remdesivir for the treatment of COVID-19 have not been established. This authorization is temporary and may be revoked, and it does not take the place of the formal new drug application submission, review and approval process. For information about the authorized use of remdesivir and mandatory requirements of the EUA in the United States, please review the Fact Sheets and FDA Letter of Authorization available at www.gilead.com/remdesivir.

There are limited clinical data available for remdesivir. Serious and unexpected adverse events may occur that have not been previously reported with remdesivir use. Hypersensitivity reactions, including infusion-related and anaphylactic reactions, have been observed during and following administration of remdesivir. The use of remdesivir 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 remdesivir. 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 remdesivir; additionally monitor serum chemistries and hematology daily during therapy. Do not initiate remdesivir in patients with ALT ≥5x ULN or with an eGFR <30 mL/min. The decision to continue or discontinue remdesivir 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 remdesivir 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 remdesivir treatment and considered to be potentially attributable to remdesivir. 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.

Gilead 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 the European Commission may not extend or convert the conditional marketing authorization into an unconditional marketing authorization for Veklury as a treatment for COVID-19. Remdesivir is an investigational drug that has not been approved by the FDA for any use, including for the treatment of COVID-19. There is the possibility of unfavorable results from ongoing and additional clinical trials involving remdesivir 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 remdesivir or that FDA and other regulatory agencies may not approve remdesivir, and any marketing approvals, if granted, may have significant limitations on its use. As a result, remdesivir may never be successfully commercialized. 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 March 31, 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.

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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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