EUROPEAN COMMISSION GRANTS CONDITIONAL MARKETING AUTHORIZATION FOR GILEAD'S VEKLURY® (REMDESIVIR) FOR THE TREATMENT OF COVID-19

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

Foster City, Calif., July 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.