



July 22, 2022

CHMP Adopts Positive Opinion Recommending Veklury® (Remdesivir) Receive Full Marketing Authorization for the Treatment of Patients With COVID-19

– If Granted by the European Commission, Veklury will Become the Only Direct-Acting Antiviral with Full Marketing Authorization in the EU –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Commission (EC) adopted a positive opinion on the fulfillment of the last specific obligation and recommended the granting of Marketing Authorization (MA) for Veklury® (remdesivir) that is no longer subject to specific obligations. Veklury was initially granted a conditional marketing authorization in July 2020 for the treatment of COVID-19 in adults and adolescents (from 12 years of age and weighing at least 40 kilograms) with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation at the start of treatment). In December of 2021, the conditional authorization was expanded to include adults who do not require supplemental oxygen and are at increased risk of developing severe COVID-19. The EC will review the CHMP recommendation and, pending adoption, Veklury will be fully authorized for these patients with COVID-19.

“We welcome the Committee’s positive opinion recommending a full marketing authorization for Veklury. Veklury continues to demonstrate durable activity against SARS-CoV-2 as it evolves, and it is the most used antiviral in hospitalized patients,” said Merdad Parsey, MD, PhD, Chief Medical Officer of Gilead. “More than two years into this pandemic, it’s critical to continue to secure access to effective treatments. We are proud of the role Veklury plays as the COVID-19 antiviral standard of care for hospitalized patients, and we remain committed to make it available to all patients that can benefit from it. We look forward to the EC’s decision.”

This positive opinion is based upon the fulfillment of the last specific obligation for Veklury, which included the review of virology data inclusive of in vitro data showing Veklury retains activity against variants of concern, including Alpha, Beta, Gamma, Delta and Omicron (BA.1 and BA.2). In addition, an assessment of the current

risk-benefit of Veklury, which considered the efficacy and safety data accumulated since the initial granting of the conditional marketing authorization, was reviewed by the CHMP to support the change to a full marketing authorization.

In the European Economic Area (EEA), Veklury is the only antiviral indicated for both the treatment of COVID-19 in adult and adolescent patients with pneumonia requiring supplemental oxygen (low- or high-flow oxygen or other non-invasive ventilation) and adults who do not require supplemental oxygen and are at increased risk of developing severe 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.