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U.S. Food and Drug Administration Approves Vemlidy® (tenofovir alafenamide) for Treatment of Chronic Hepatitis B Virus Infection in Pediatric Patients

– Approval Expands on Previous FDA Approval of Vemlidy in Adults Living With This Chronic Liver Disease –

– Efficacy and Safety of Once-Daily Vemlidy Demonstrated in Individuals 12 Years of Age and Older –

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental new drug application (sNDA) for Vemlidy® (tenofovir alafenamide) 25 mg tablets as a once-daily treatment for chronic hepatitis B virus (HBV) infection in pediatric patients 12 years of age and older with compensated liver disease.

Vemlidy is a novel, targeted prodrug of tenofovir that was previously approved by the FDA in 2016 as a once-daily treatment for adults with chronic HBV infection with compensated liver disease. It is recommended as a preferred or first-line treatment for adults with chronic HBV with compensated liver disease in guidelines from the American Association for the Study of Liver Diseases (AASLD) and European Association for the Study of the Liver (EASL).1,2

Vemlidy's approval in this pediatric patient population is supported by 24-week data from a Phase 2 clinical trial (Trial 1092) comparing treatment with Vemlidy 25 mg to placebo among 70 treatment-naïve and treatment-experienced patients aged 12 to less than 18 years weighing at least 35 kg. The study met its primary endpoint of percentage of patients with HBV DNA levels below 20 IU/mL at 24 weeks of therapy; overall, 21% (10/47) of subjects treated with Vemlidy 25 mg achieved HBV DNA <20 IU/mL at 24 weeks compared to 0% (0/23) of subjects treated with placebo.

"Chronic hepatitis B can have a significant long-term health impact on children, including the development of liver cancer later in life if the disease is left untreated, which is compounded by treatment challenges in this population," said Kathleen

Schwarz, MD, Pediatric Gastroenterologist, Rady Children's Hospital-San Diego, an investigator in the Vemlidy clinical trial. "As a clinician, I recognize the critical importance of treating this disease as quickly as possible to help avoid complications and potential damage to the liver. In the clinical trial, we saw that tenofovir alafenamide may represent an effective treatment option for people as young as 12 years of age living with this chronic disease."

"While pediatric hepatitis B prevalence has dropped significantly in the U.S., children who develop chronic hepatitis B following an acute infection can experience lifelong health impact," said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. "Gilead is focused on meeting the biggest challenges in liver disease and impacting the course of disease. With an established safety profile and once-daily dosing, Vemlidy provides physicians a new option to address the treatment needs of pediatric patients living with hepatitis B."

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.

About Gilead Sciences

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