FDA APPROVES VEKLURY® (REMDESIVIR) FOR THE TREATMENT OF NON-HOSPITALIZED PATIENTS AT HIGH RISK FOR COVID-19 DISEASE PROGRESSION

-- Approval Based on Phase 3 Data Showing Veklury Significantly Reduced Risk of Hospitalization By 87% Compared with Placebo --

-- NIH Guidelines Recommend Veklury for the Treatment of Non-Hospitalized Patients at High Risk --

-- FDA Expands Pediatric Emergency Use Authorization (EUA) to Include Treatment of Non-Hospitalized Pediatric Patients at High Risk –

***** Veklury® (Remdesivir) has not been approved in China yet.

FOSTER CITY, Calif.--(BUSINESS WIRE)-- Gilead Sciences, Inc. (Nasdaq: GILD) today announced that the U.S. Food and Drug Administration (FDA) has granted expedited approval of a supplemental new drug application (sNDA) for Veklury® (remdesivir) for the treatment of non-hospitalized adult and adolescent patients who are at high risk of progression to severe COVID-19, including hospitalization or death. This approval expands the role of Veklury, which is the antiviral standard of care for the treatment of patients hospitalized with COVID-19. The expanded indication allows for Veklury to be administered in qualified outpatient settings that can administer daily intravenous (IV) infusions over three consecutive days. The FDA has also expanded the pediatric Emergency Use Authorization (EUA) of Veklury to include non-hospitalized pediatric patients younger than 12 years of age who are at high risk of disease progression.

These actions by the FDA come amidst a surge in COVID-19 cases and the reduced susceptibility to several anti-SARS-CoV-2 monoclonal antibodies (mAbs) due to the Omicron variant. In contrast, Veklury targets the highly conserved viral RNA polymerase, thereby retaining activity against existing SARS-CoV-2 variants of concern. *In vitro* laboratory testing shows that Veklury retains activity against the Omicron variant. To date, no major genetic

changes have been identified in any of the known variants of concern that would significantly alter the viral RNA polymerase targeted by Veklury.

The FDA sNDA approval, pediatric EUA expansion and recently updated National Institutes of Health (NIH) Treatment Guidelines for COVID-19 that additionally recommend Veklury for treatment in non-hospitalized settings, are based on results from the PINETREE Phase 3 randomized, double-blind, placebo-controlled trial. The trial evaluated the efficacy and safety of a three-day course of Veklury for intravenous (IV) use for the treatment of COVID-19 in non-hospitalized patients at high risk for disease progression. An analysis of 562 participants randomly assigned in a 1:1 ratio to receive Veklury or placebo, demonstrated that treatment with Veklury resulted in a statistically significant 87% reduction in risk for the composite primary endpoint of COVID-19 related hospitalization or all-cause death by Day 28 (0.7% [2/279]) compared with placebo (5.3% [15/283]) p=0.008. In the study, no deaths were observed in either arm by Day 28. The safety profile was similar between Veklury and placebo across the variety of outpatient settings in this trial, with the most common treatment emergent adverse events (≥5%) in patients taking Veklury being nausea and headache.

“Remdesivir has now helped to treat more than 10 million people around the world with COVID-19 and continues to play a key role in helping to reduce the burden of the pandemic. Based on the most recent data, we now understand that remdesivir is also effective in the early stages of COVID-19 infection, in addition to helping patients who are hospitalized with the disease,” said Daniel O’Day, Chairman and Chief Executive Officer, Gilead Sciences. “While we continue to advance remdesivir to benefit more patients in multiple settings, we are also advancing our investigational oral compounds. These are based on the same antiviral mechanism of action as remdesivir and a Phase 1 trial for our oral COVID-19 antiviral, GS-5245 is now underway.”

In the United States, Veklury is indicated for the treatment of COVID-19 in adults and pediatric patients (12 years of age and older and weighing at least 40 kg) who are either hospitalized *or* not hospitalized and are at high risk for progression to severe COVID-19, including hospitalization or death. Veklury is additionally authorized for these uses under the EUA for pediatric patients weighing 3.5 kg to less than 40 kg *or* pediatric patients less than 12

years of age weighing at least 3.5 kg. Veklury is contraindicated in patients who are allergic to Veklury or any of its components.

Under the expanded indication for Veklury, non-hospitalized adult and pediatric patients (12 years of age and older and weighing at least 40 kg) with confirmed SARS-CoV-2 infection who are at high risk for COVID-19 disease progression can be treated with a recommended treatment duration of three days to help prevent hospitalization. For hospitalized patients not on mechanical ventilation and/or ECMO, a 5-day course of treatment is recommended, with the option to extend to a total of 10-days as needed. Critically ill patients who require mechanical ventilation and/or ECMO should receive a 10-day course of treatment.

Updates to Veklury Distribution in the U.S.

Gilead has been meeting U.S. and global demand for Veklury for the treatment of hospitalized patients, without disruption since October 2020 after FDA approval. Gilead will now work with distributors to make Veklury available in qualified outpatient facilities, including providing product information to non-hospital settings, to help meet the unprecedented demand for early treatment options brought on by the current COVID-19 surge. In accordance with the recommendations provided by the National Institutes of Health (NIH) COVID-19 Treatment Guidelines, which prioritize treatment for those patients who are at the highest risk of progressing to severe COVID-19, our goal is to continue to ensure uninterrupted supply for inpatient hospital use while expanding to outpatient facilities as well. Gilead will enable outpatient ordering in a tiered approach that will start with hospital outpatient departments due to their experience and familiarity with the administration of Veklury; then outpatient ordering will be available to other qualified outpatient facilities.