

## **GILEAD SCIENCES STATEMENT ON THE SOLIDARITY TRIAL**

We are aware that initial data from the World Health Organization's (WHO) SOLIDARITY Trial has been made public prior to publication in a peer-reviewed journal. The emerging data appear inconsistent with more robust evidence from multiple randomized, controlled studies published in peer-reviewed journals validating the clinical benefit of Veklury® (remdesivir). We are concerned that the data from this open-label global trial have not undergone the rigorous review required to allow for constructive scientific discussion, particularly given the limitations of the trial design. The SOLIDARITY Trial is a multi-center, open-label global trial that provided early access to Veklury, among other investigational COVID-19 treatments, to patients around the world - particularly in countries where ongoing trials of investigational treatments were not available. The trial design prioritized broad access, resulting in significant heterogeneity in trial adoption, implementation, controls and patient populations and consequently, it is unclear if any conclusive findings can be drawn from the study results.

The benefits of Veklury have been demonstrated in three randomized, controlled clinical trials, including a randomized, double-blind, placebo-controlled clinical trial (ACTT-1) – the gold standard for evaluating the efficacy and safety of investigational drugs. The results from the National Institute for Allergy and Infectious Diseases (NIAID)'s ACTT-1 trial, which was conducted primarily in the United States and Europe, found that treatment with Veklury resulted in clinically meaningful improvements across multiple outcome assessments in hospitalized COVID-19 patients. These data were peer-reviewed and published in the [\*New England Journal of Medicine\*](#) and have supported Veklury's inclusion in multiple treatment guidelines. These data have also supported regulatory approvals or temporary authorizations to treat COVID-19 in approximately 50 countries worldwide. Additionally, we are pleased that today WHO has prequalified remdesivir, which assures procurement agencies such as the United Nations that Veklury has met global standards of quality, safety and efficacy.

### Important Information about Veklury in the United States

Veklury has not been approved by the U.S. Food and Drug Administration (FDA) for any use, and its safety and efficacy have not been established. Gilead submitted a new drug application for Veklury on August 7, 2020; the NDA is currently under FDA review. Veklury is currently authorized for temporary use under an Emergency Use Authorization (EUA) for the treatment of hospitalized patients with COVID-19, including patients with moderate to severe disease, regardless of the need for supplemental oxygen. This authorization is temporary and may be revoked, and does not take the place of the formal new drug application submission, review and approval process. For information about the authorized use of Veklury and mandatory requirements of the EUA in the U.S., please review the Fact Sheets and FDA Letter of Authorization available at [www.gilead.com/remdesivir](http://www.gilead.com/remdesivir).

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