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Creating Possible

Dear MEB, RIVM and VWS,

GILEAD SCIENCES STATEMENT ON THE SOLIDARITY TRIAL

Gilead would like to inform the MEB and RIVM that initial data from the World Health Organization's (WHO) SOLIDARITY Trial has been made public on the medRxiv website (https://www.medrxiv.org/content/10.1101/2020.10.15.20209817v1) as a preprint prior to publication in a peer-reviewed journal. Pursuant to medRxiv media policy, "[p]reprints are preliminary reports of work that have not been certified by peer review [and] they should not be relied on to guide clinical practice or health-related behavior and should not be reported in news media as established information."

The emerging data in the attached paper from the medRxiv website 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.

Gilead is currently seeking additional insight from the WHO regarding data from the SOLIDARITY trial. A further update will be provided after receipt of the complete data from the WHO, or publication in a peer-reviewed journal.

Sincerely,

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