An Open Letter from Daniel O'Day, Chairman & CEO, Gilead Sciences

When the news of the coronavirus first emerged, Gilead immediately began to investigate the potential of remdesivir, a medicine we had been studying for many years as part of our extensive research in antivirals. Remdesivir had never been approved for use but based on what we had learned to date, we knew it might have potential with the novel coronavirus. Since then, we have been working with the greatest sense of urgency and responsibility to determine whether remdesivir does indeed work against COVID-19.

The urgency comes from knowing the desperate need among patients and the lack of any approved treatment. The responsibility is to ensure that remdesivir, an investigational medicine, is effective and safe before it is distributed for use worldwide.

This is why we have been working at unprecedented speed to enroll patients in clinical trials. Establishing the safety and efficacy of remdesivir, in partnership with regulatory authorities, is essential to potentially enabling the treatment of many more patients in the future. Multiple studies are ongoing, and we are on track to have initial data in the coming weeks. If it is approved, we will work to ensure affordability and access so that remdesivir is available to patients with the greatest need.

In the meantime, we have made the investigational medicine available for severely ill patients who cannot enroll in a trial. This "compassionate use" program is typically reserved for a small number of individual cases but there is nothing typical about this crisis and to date we have provided remdesivir to more than 1,000 patients. The program is designed by regulatory authorities in such a way that each application has to be reviewed on an individual basis. This works well when there is only a limited number of requests – as is normally the case – but the system cannot support and process the overwhelming number of applications we have seen with COVID-19.

To address this, we are transitioning to what should be a more streamlined, sustainable approach with "expanded access" programs. The compassionate use program will continue for children and pregnant women only, reducing the numbers to a level where the system can cope. With expanded access, hospitals or physicians can apply for emergency use of remdesivir for multiple severely ill patients at a time. While it will take some time to build a network of active sites, this approach will ultimately accelerate emergency access for more people. Initial sites in the United States are up and running as of yesterday, and it is expected that sites in additional countries will be activated soon.

In recent days, many people have reached out to Gilead to advocate for access to remdesivir on behalf of friends and loved ones. I can only imagine how it must feel to be in that situation. We are used to seeing numbers and statistics in the news on a daily basis but we all know that behind each of those numbers is a real and often heartbreaking human story. I know I speak for everyone at Gilead when I say how much we all wish we could help every patient in need. Today we are working at speed to establish the temporary expanded access programs, while at the same time establishing the potential safety and efficacy of remdesivir and determining for which patients remdesivir may have activity.

Remdesivir is still an investigational medicine. We are planning for the outcome we all hope for – that it will prove to be a safe, effective treatment – and in the meantime we are taking the ethical, responsible approach to determining whether that is the case. At each step of the way, our decisions are informed by

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guidance from public health authorities and bioethicists, and by our decades of experience in making antiviral treatments for diseases such as HIV and viral hepatitis.

We hope that, in partnership with many groups around the world, we can play a part in helping patients with this disease. We know how much is at stake and the urgent need to determine whether remdesivir will be a safe and effective treatment.

We think about the healthcare workers who are on the front lines of fighting this pandemic around the clock and the urgent need to equip them with a treatment. We know that patients and their families around the world are waiting. All of us at Gilead are doing everything we can to meet our responsibility with remdesivir, with the greatest sense of urgency and care.

As we continue with those efforts, we will provide updates on our progress as soon as information becomes available, recognizing the significant public interest in remdesivir around the world.

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