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

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Over the past two months we all have been waiting in hopeful anticipation for the science to speak on remdesivir. While there were clues along the way, we knew that only clinical trials could provide the answers on whether it is a safe and effective treatment for COVID-19. Today we have some initial answers.

The results from the global, placebo-controlled trial run by the National Institute of Allergy and Infectious Diseases (NIAID) are positive. They show that patients with COVID-19 who received remdesivir recovered faster than similar patients who received placebo.

There is still more work to do and remdesivir has not been approved, but all of us at Gilead are humbled by what these promising results might mean for patients. After years of research and hard work on remdesivir, there is relief and gratitude among our teams today that their efforts have been so worthwhile.

This work started long before we knew about the outbreak of COVID-19. Remdesivir is the result of more than a decade of research, experimentation and iteration by Gilead scientists. In recent years, we have been studying its impact in hemorrhagic fever viruses such as Ebola, Marburg and Nipah viruses as well as other coronaviruses such as SARS and MERS. We had built up sufficient knowledge so that when the novel coronavirus emerged, we could move very quickly into clinical trials.

Since January, our teams have been working day and night to determine whether remdesivir might work in patients with COVID-19. These efforts include collaboration with study investigators and governments on the various clinical trials. Today's news, that remdesivir might play a role in easing the burden of the pandemic, is the outcome we all hoped would be possible.

Today's results in context

The NIAID study is part of a suite of clinical trials to investigate the effects of remdesivir. When we designed the overall clinical program, we did so in such a way that we could ask multiple questions in parallel, including which groups of patients are most likely to respond, when to treat and for how long. Various study designs were used from placebo-controlled to open-label to answer very specific questions in each case. We expected that the answers would emerge around the same time and that, taken together, they would form a clear picture of how remdesivir might best be used for patients.

Today, in addition to the NIAID data on safety and efficacy, we also have data regarding duration of treatment from the Gilead-sponsored Phase 3 SIMPLE trial in patients with severe COVID-19 disease. The question of duration is important because the possibility of a shorter treatment course is beneficial in many respects. Patients can return home earlier from the hospital, families can be reunited, healthcare resources are freed up and more medicine is available for other patients in need. In a time of pandemic, all of this becomes especially significant.

The SIMPLE clinical trials have been evaluating whether five days of treatment with remdesivir would result in the same outcomes as 10 days. The data from the first study showed similar clinical improvements in patients with severe symptoms of COVID-19, regardless of whether they received five or 10 days of treatment. We are very pleased with these results. They provide valuable information on treatment duration in this severe patient population and show the outcome we had all hoped to see.

This outcome has positive implications for our supply of remdesivir. Our teams have been ramping up production since January, working within all the constraints that come with such a lengthy and complex manufacturing process. Our existing supply, including finished product ready for distribution as well as materials in the final stages of production, amounts to 1.5 million individual doses. We had estimated that this would be 140,000 treatment courses based on a 10-day treatment duration. The ability to shorten duration for severely ill patients means we can significantly increase the number of courses available, all of which Gilead has committed for donation.

From the two sets of results today - the NIAID and SIMPLE data - we now know two things: that remdesivir appears to shorten time to recovery and when treating patients with severe disease, a five-day treatment course is potentially as effective as 10 days.

The path forward
The story of remdesivir always has been one of collaboration and letting the science speak and these will continue to shape our approach.

Today's results open up many opportunities to explore the utility and potential of remdesivir. Our teams will look at ways to potentially bring the treatment to a broader patient population by investigating other formulations and means of delivery. We will also engage with partners to explore how remdesivir might work with other therapies.

On the supply side, we are working to build a global consortium of pharmaceutical and chemical manufacturers to expand global capacity and production. It will be essential for countries to work together to create enough supply for people all over the world and we look forward to these collaborative efforts. In the event of regulatory action, we are in discussions with various groups about how we might bring remdesivir to the developing world.

Thank you to everyone who has helped to bring us this far with remdesivir – from the patients involved in clinical trials to healthcare workers, study investigators and many other groups. We know that there is still a lot of work to be done and a long way to go in finding medical solutions to stop the pandemic. At the same time, today's news on remdesivir represents important progress and offers hope at a time when it is badly needed.

Forward-Looking Statement

This statement includes forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors. Remdesivir is an investigational agent that has not been licensed or approved anywhere globally, and it has not been demonstrated to be safe or effective for any use, including for the treatment of COVID-19. There is the possibility of unfavorable results from ongoing and additional clinical trials involving remdesivir and the possibility that Gilead and other parties may be unable to complete one or more of such trials in the currently anticipated timelines or at all. Further, it is possible that Gilead may make a strategic decision to discontinue development of remdesivir or that FDA and other regulatory agencies may not approve remdesivir, and any marketing approvals, if granted, may have significant limitations on its use. As a result, remdesivir may never be successfully commercialized. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's periodic reports filed with the U.S. Securities and Exchange Commission, including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports

on Form 10-K. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.