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

June 29, 2020

FOSTER CITY, Calif.--(BUSINESS WIRE)--Jun. 29, 2020-- In the weeks since we learned of remdesivir’s potential against COVID-19, one topic has attracted more speculation than any other: what price we might set for the medicine. This degree of speculation is understandable. Remdesivir, our investigational treatment, is the first antiviral to have demonstrated patient improvement in clinical trials for COVID-19 and there is no playbook for how to price a new medicine in a pandemic. We are aware of the significant responsibility that comes with pricing remdesivir, and the need to be transparent on our decision. After giving this the considerable care, time and amount of discussion that it merits, we are now ready to share our decision and explain how we reached it.

As with all our actions on remdesivir, we approached this with the aim of helping as many patients as possible, as quickly as possible and in the most responsible way. This has been our compass point throughout, from collaborating to find rapid answers on safety and efficacy, to scaling up manufacturing and donating our supply of remdesivir through the end of June. In each case, we recognized the need to do things differently to reflect the exceptional circumstances of the pandemic. Now, as we transition beyond the donation period and set a price for remdesivir, the same principle applies.

In normal circumstances, we would price a medicine according to the value it provides. The first results from the NIAID study in hospitalized patients with COVID-19 showed that remdesivir shortened time to recovery by an average of four days. Taking the example of the United States, earlier hospital discharge would result in hospital savings of approximately $12,000 per patient. Even just considering these immediate savings to the healthcare system alone, we can see the potential value that remdesivir provides. This is before we factor in the direct benefit to those patients who may have a shorter stay in the hospital.

We have decided to price remdesivir well below this value. To ensure broad and equitable access at a time of urgent global need, we have set a price for governments of developed countries of $390 per vial. Based on current treatment patterns, the vast majority of patients are expected to receive a 5-day treatment course using 6 vials of remdesivir, which equates to $2,340 per patient.

Part of the intent behind our decision was to remove the need for country by country negotiations on price. We discounted the price to a level that is affordable for developed countries with the lowest purchasing power. This price will be offered to all governments in developed countries around the world where remdesivir is approved or authorized for use. At the current price of $390 per vial, remdesivir is positioned to achieve the aim of providing immediate net savings for healthcare systems.

In the U.S., the same government price of $390 per vial will apply. Because of the way the U.S. system is set up and the discounts that government healthcare programs expect, the price for U.S. private insurance companies, will be $520 per vial. At the level we have priced remdesivir and with government programs in place, along with additional Gilead assistance as needed, we believe all patients will have access.

Gilead has entered into an agreement with the U.S. Department of Health and Human Services (HHS) whereby HHS and states will continue to manage allocation to hospitals until the end of September. After this period, once supplies are less constrained, HHS will no longer manage allocation.

In the developing world, where healthcare resources, infrastructure and economics are so different, we have entered into agreements with generic manufacturers to deliver treatment at a substantially lower cost. These alternative solutions are designed to ensure that all countries in the world can provide access to treatment.

Our work on remdesivir is far from done. We continue to explore its potential to help in this pandemic in various ways, such as evaluating treatment earlier in the course of the disease, in outpatient settings, with an inhaled formulation, in additional patient groups and in combination with other therapies. As we accumulate more data from global clinical trials and initiate many additional studies, we will understand more about the full value of remdesivir over time. Our teams also remain focused on increasing supplies to meet the high global demand. By the end of this year, we expect our investment on the development and manufacture of remdesivir to exceed $1 billion (U.S.) and our commitment will continue through 2021 and beyond.

In making our decision on how to price remdesivir, we considered the full scope of our responsibilities. We started with our immediate responsibility to ensure price is in no way a hindrance to ensuring rapid and broad treatment. We also balanced that with our longer-term responsibilities: to continue with our ongoing work on remdesivir, to maintain our long-term research in antivirals and to invest in scientific innovation that might help generations to come. As with many other aspects of this pandemic, we are in unchartered territory in pricing remdesivir. Ultimately, we were guided by the need to do things differently. As the world continues to reel from the human, social and economic impact of this pandemic, we believe that pricing remdesivir well below value is the right and responsible thing to do.

About Remdesivir

Remdesivir is an antiviral product that is being studied in multiple ongoing international clinical trials. In recognition of the current public health emergency and based on available clinical data, the approval status of remdesivir varies by country. In countries where remdesivir has not been approved by the regional health authority, remdesivir is an investigational drug, and the safety and efficacy of remdesivir have not been established.

Remdesivir has not been approved by the U.S. Food and Drug Administration (FDA) for any use. In the U.S., the FDA granted remdesivir an Emergency Use Authorization (EUA) for the treatment of hospitalized patients with severe COVID-19. 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 remdesivir 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.

About Gilead Sciences

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of
unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California.

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 approved by the FDA for any use, and it has not been demonstrated to be safe or effective 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. In addition, Gilead may face challenges related to the allocation and geographical distribution of existing and future supply of remdesivir. If Gilead is unable to sufficiently scale up production of remdesivir in the currently anticipated timelines, Gilead may be unable to meet future supply needs. 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2020 as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

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