FREQUENTLY ASKED QUESTIONS ON REMDESIVIR PRICING AND GLOBAL SUPPLY

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Remdesivir, an investigational, intravenous treatment for COVID-19, is the first antiviral to have demonstrated patient improvement in Phase 3 clinical trials. Data demonstrate that remdesivir helps hospitalized patients to recover more quickly, potentially freeing up provider time and hospital resources, and saving the healthcare system money. In the National Institute of Allergy and Infectious Diseases' randomized, placebo-controlled study, remdesivir reduced recovery time of hospitalized patients by a median of four days. In the United States, for example, reducing hospitalization by four days equates to a potential savings of approximately $12,000.

Gilead's goal is to work with health authorities to ensure rapid and broad access to remdesivir to help ease the significant burden that COVID-19 has brought to the world. Remdesivir has been approved for use in Japan, Taiwan, India, Singapore, the United Arab Emirates and the European Union.[1] In the United States, the FDA has granted remdesivir an Emergency Use Authorization for the treatment of hospitalized patients with severe COVID-19.

On June 29, 2020, Gilead announced the pricing for remdesivir, following the donation of 1.5 million vials of the drug, which represented our entire supply of the drug through the end of June. Given the unique situation of this global pandemic, we have set the government pricing for remdesivir in developed countries significantly below the potential overall value that remdesivir provides. In doing so, we ensure remdesivir is accessible and affordable to patients, while also balancing the need to recoup our investment to date and continue to invest in this medicine and research that will prepare us for emerging pandemic threats.

Why did you announce two prices for remdesivir?
We have set the government price of remdesivir at $390 per vial or $2,340 per 5-day treatment course in developed countries. In the United States, we have also set a list price for commercial insurers of $520 per vial or $3,120 per 5-day treatment course. We announced two prices for remdesivir in the United States because of the way the U.S. system is set up and the discounts that government healthcare programs expect. By enabling patients to recover more quickly, which potentially frees up provider time and hospital resources, remdesivir can save the healthcare system money.

In the United States, the government price is applicable to federal agencies that directly purchase drugs, such as the Veterans' Affairs, Indian Health Services, Department of Defense, the Coast Guard and the Federal Bureau of Prisons, once on the Federal Supply Schedule. Medicare and Medicaid are not direct purchasers of drugs administered in an inpatient setting. Instead, hospitals purchase inpatient drugs at commercial pricing and are then reimbursed by the Centers for Medicare & Medicaid Services at set rates as part of a bundled payment for all hospital services.

What will U.S. patients pay for remdesivir in the United States, where there is no universal healthcare system?
The list and government prices for remdesivir are not what patients pay. We do not expect affordability to be an issue for patients because of government efforts in place for COVID-19 patients, healthcare insurers and additional assistance that Gilead will provide as needed.

For patients with commercial insurance
Patients' out-of-pocket costs will be determined by individual health plans. The healthcare insurance industry has responded to the pandemic to support patients who need COVID-19 treatment, with many companies waiving out-of-pocket costs. More information is available at https://www.ahip.org/health-insurance-providers-respond-to-coronavirus-covid-19/.

For patients with government plans
Patients do not pay directly for hospital-administered drugs like remdesivir.

For patients without insurance
For the uninsured, the CARES Act created a Provider Relief Fund that helps hospitals provide uninsured patients with access to COVID-19 treatments without any out-of-pocket costs. Hospitals may submit claims to the Provider Relief Fund for reimbursement for the treatment of uninsured patients with COVID-19, and if the hospital submits a claim, it cannot bill the patient for any remaining costs that may result from their stay.

We are hopeful that hospitals will seek to access this funding for patient treatment needs, including remdesivir. To support uninsured patients whose hospital does not submit a claim to the Provider Relief Fund, we are offering a program that will provide free product for such uninsured, eligible patients.

[1] The European Commission granted remdesivir a conditional marketing authorization, which enables the drug to be marketed for a period of one year. The authorization can be renewed annually until confirmatory data are submitted and standard marketing authorization is granted.

How much will remdesivir cost in the developing world?
We have entered into non-exclusive voluntary licensing agreements with nine generic manufacturers to further expand access and supply of remdesivir in 127 countries classified as lower-income or that face significant obstacles to healthcare access. These generic manufacturers will be free to set their own prices. It is our hope and intent that volumes and competition will drive costs down.

In regions of high need that are not currently covered by these agreements, we are exploring a number of innovative strategies to support access to remdesivir. We also are continuing to discuss with UNICEF and other organizations the possibility of donating and/or distributing remdesivir for use in low- and middle-income countries. We hope to finalize these arrangements soon.

How much has Gilead invested to date in the development of remdesivir?
This year alone, Gilead's investment could exceed $1 billion. This does not include the investment we have made in the development of the drug, which began more than a decade ago. We have also invested significantly to conduct and support studies to evaluate remdesivir's efficacy and safety, and to shorten manufacturing timelines, expand our international supply chain and ramp up manufacturing of this investigational drug to support global demand. We continue to invest heavily in further studies and the development of new formulations with the goal of extending the medicine's benefit to additional patients in need.

Are U.S. taxpayers paying twice for remdesivir because the U.S. government has already invested in its development?
No. Gilead scientists invented remdesivir with research that started more than a decade ago. Our scientists identified its broad-spectrum antiviral activity, optimized the formulation of the product and scaled up the manufacturing process. Our research and development are fundamental to remdesivir's use to treat COVID-19, and our investment in the research and development of remdesivir is significantly greater than investment from public sources.

We value our collaboration with government partners who helped further characterize remdesivir's profile after Gilead's initial discovery. To our knowledge, government grants totaling approximately $18.9 million have been made to academic collaborators of Gilead for work relating to coronaviruses – a portion of which was used to support their work with Gilead on remdesivir. To provide context, government grants for collaborative research into coronaviruses was less than two percent of the investment Gilead expects to make specifically in remdesivir this year alone.

The $76 million figure that has been quoted publicly relates to the total amount of government grants given to Gilead's academic collaborators for their research across many disease areas. This figure does not include the cost of the National Institute of Allergy and Infectious Diseases' ongoing clinical studies of remdesivir, for which Gilead donated study drug and provided input.

How much remdesivir will be available in the United States and for other countries over the next few months?
Gilead has agreed to supply more than 500,000 treatment courses for use in the United States through the end of September. This allocation was determined after discussion with the U.S. government about the significant rise in incidence of COVID-19 within the United States and the urgent need to help treat patients impacted by the recent increased outbreaks. We recognize the global scale of this pandemic and are working as quickly as possible to enable access around the world. We expect our global supply will be less constrained by the end of September and that, at currently anticipated rates of infection, our supply in October and beyond will meet real-time global demand.

We have agreed with the U.S. government that unallocated portions of supply through September can be allocated for other uses, including to countries outside of the United States. As we have previously communicated, we have invested significantly to shorten manufacturing timelines, expand our international supply chain and ramp up manufacturing of this investigational drug to support global demand. To the extent that our manufacturing teams are able to produce more remdesivir than currently anticipated over the summer, we will have additional supply outside the United States.

How will remdesivir be allocated in the United States?
The Department of Health and Human Services and state governments will continue to manage allocation of remdesivir to U.S. hospitals until the end of September. AmerisourceBergen will distribute the drug to hospitals identified by the U.S. government. After September, once supplies are less constrained, HHS will no longer manage allocation and we will transition to a more traditional supply chain.

Remdesivir has not been approved by the U.S. 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.

How will remdesivir be allocated outside of the United States?
Access to remdesivir will be prioritized first according to regulatory approvals and authorizations and the incidence of disease, and subsequently by severity of disease, to provide access to patients with the most urgent need for treatment.