

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

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Over the course of the past week, Gilead has been working in consultation with regulatory authorities to establish additional expanded access programs for remdesivir, our investigational medicine for COVID-19. The programs enable hospitals or physicians to apply for emergency use of remdesivir for multiple severely ill patients at a time. These are patients who cannot take part in clinical trials and where the word “emergency” is all too real for them, their families and the healthcare providers advocating on their behalf.

We know the desperate urgency of reaching these patients and believe that the expanded access program will help to accelerate the process. New U.S. sites have been initiated and we are adding more on an ongoing basis. We are also making progress in Europe. Yesterday, the European Medicines Agency announced that it has provided EU member states with recommendations on implementing expanded access programs for remdesivir in their countries.

In addition to the expanded access programs, we continue to provide remdesivir on an individual compassionate use basis for children and pregnant women. More than 1,700 patients have now been treated through these programs.

Remdesivir is still an investigational medicine and has not been approved by regulatory authorities anywhere in the world. The safety and efficacy are not yet known, so while we feel the greatest sense of urgency in our work with remdesivir, we must take the responsible, ethical approach of determining whether it is indeed a safe, effective treatment. This is why multiple clinical trials for remdesivir are underway, involving thousands of patients with COVID-19 across the world.

We know from the heartbreaking letters we receive, the images we see in the news and the all-too-bleak statistics that the urgency to find broad, effective solutions becomes more intense each day. In the ways we believe it is appropriate for Gilead to play a role today - primarily through clinical trials, as well as expanded access and compassionate use - we are doing everything it takes to meet our significant responsibility with remdesivir.

Supply and Donation of Remdesivir

A critical part of Gilead’s responsibility today is ensuring sufficient supply of remdesivir. To provide product for trials, compassionate use and expanded access, we needed to effectively start from ground zero in ramping up our supplies. The progress we have made on this to date is thanks to the actions we have been taking since January to rapidly expand production and increase supply.

As soon as we knew that remdesivir may have potential in treating the novel coronavirus, our teams began to establish a supply chain for large-scale production. Then, as now, there were many unknowns including how long the outbreak would last, at what scale and whether remdesivir is a safe and effective treatment for COVID-19. We made the decision to invest and scale up regardless, because if remdesivir was going to be needed for patients, we had to be ready.

We knew there would be challenges in producing the amounts we would ideally want to deliver in a short timeframe. One of these challenges is the length of time it takes to produce remdesivir. It is a linear process that requires specialized chemistry and multiple chemical reactions, some of which can take several weeks to complete. It also calls for scarce raw materials as well as sterile manufacturing capabilities with limited global capacity, which are needed to make finished vials ready for administration to patients.



Working within these parameters, our teams have found multiple ways of accelerating production. These include process improvements that cut production times. As a result, we have reduced the end-to-end manufacturing timeline from approximately one year, to around six months. We have repurposed some of our own facilities to focus on remdesivir and we have also increased our network of external manufacturing partners around the world.

In the space of two months, we have significantly increased our available supply of remdesivir using the inventory of active pharmaceutical ingredients we already had on hand. Our existing supply, including finished product ready for distribution as well as investigational medicine in the final stages of production, amounts to 1.5 million individual doses. Depending on the optimal duration of treatment, which is something we are studying in clinical trials, this supply could equate to well over 140,000 treatment courses for patients.

Our efforts to increase supply continue with a strong sense of urgency. There is a long way to go and a lot of work to be done but I'm pleased that, despite the challenges we have been able to get supply levels to where they are today in a very short space of time - through the resourcefulness of our teams, creative approaches and collaboration.

Gilead is providing the entirety of this existing supply at no cost, to treat patients with the most severe symptoms of COVID-19. The 1.5 million individual doses are available for compassionate use, expanded access and clinical trials and will be donated for broader distribution following any potential future regulatory authorizations. These doses are for treating patients with severe symptoms, through daily intravenous infusions in a hospital setting. Having a potential treatment in our hands comes with significant responsibility. Providing our existing supplies at no charge is the right thing to do, to facilitate access to patients as quickly as possible and in recognition of the public emergency posed by this pandemic.

Looking Forward

While we are working with the utmost sense of urgency on the immediate needs before us, we are also looking forward. Over the next weeks and months, we will be able to further increase our supplies of remdesivir as raw materials with long lead times become available for manufacture. We have set an ambitious goal of producing more than 500,000 treatment courses by October and more than 1 million treatment courses by the end of this year.

To help us meet and exceed this goal, we are building a geographically diverse consortium of pharmaceutical and chemical manufacturers to expand global capacity for raw materials and production. This collaboration will allow us to achieve far more than any of us could have done working alone. The international nature of the supply chain for remdesivir reminds us that it is essential for countries to work together to create enough supply for the world.

These are intense, ongoing efforts and while they continue, we must await the data from the clinical trials before we know whether remdesivir is a safe and effective treatment.

In the meantime, in the face of many unknowns and the exceptional circumstance of this pandemic, we are finding every means possible to meet our responsibilities with remdesivir today, and to be prepared for meeting the needs of patients in the future.