



Mission and Core Values

Partnerships and Community

Giving

Sustainability

Advancing Global Health

HCV Elimination

COVID-19

Medication Access

Working to Supply Remdesivir for COVID-19

Since the moment the novel coronavirus that causes COVID-19 was identified, Gilead has mobilized every area of our organization to respond to the global health emergency. We are harnessing our decades of expertise in antiviral research and development, including more than 10 years of work on remdesivir specifically, to advance a potential treatment for COVID-19 and help meet the ever-growing patient needs, should the medicine receive emergency authorizations or regulatory approvals around the world

Learn more about the development of remdesivir.

Manufacturing Process

Since January, Gilead has invested significant capital to establish a supply chain capable of large-scale production of remdesivir.

The production of remdesivir is a long, linear chemical synthesis process that must be completed sequentially and includes several specialized chemistry steps and novel substances with limited global availability. The process is both resource- and timeintensive, with some individual manufacturing steps taking weeks to complete. Because remdesivir is administered intravenously. production also requires sterile drug product manufacturing capabilities, which limits the number of organizations capable of manufacturing the medicine. This complex process impacts the ability to rapidly produce large quantities of drug supply in an emergency situation like the COVID-19 pandemic. In light of these realities, Gilead worked early on, before any clinical trials had started, to procure a steady flow of long-lead-time raw materials that will accelerate large-scale production of remdesivir by our current and future partners once these materials become available in significant quantities.

Over the last several weeks, we have also worked to shorten the manufacturing timeline through process improvements. The typical timeline for manufacturing a drug like remdesivir at scale is nine to 12 months; we have reduced that period to six to eight months. We continue to work on optimizing the chemical synthesis processes to further accelerate product deliveries and volumes.

Current and Projected Supply

As of January 2020, we were not actively manufacturing remdesivir. The manufacturing supply chain was scaled to periodically make small amounts of product for a compound in early development. We had inventory of finished product to treat just 5,000 patients.

Since then, we have proactively and rapidly scaled our supply chain. As of late March, using the active ingredient we already had in our inventory, we have increased our supply to more than 30,000 patient courses of remdesivir on hand, assuming a 10-day

course of treatment for patients. As new raw materials arrive over the next few weeks from manufacturing partners around the world, our available supply will begin to rapidly increase.

Every day we are improving processes, shortening timelines and increasing volumes as we work to bring remdesivir to patients as soon as possible. Our goal is to produce a total of:

- More than 140,000 treatment courses by the end of May 2020
- More than 500,000 treatment courses by October 2020
- More than 1 million treatment courses by December 2020
- · Several million treatment courses in 2021, if required

The numbers above are based on a 10-day treatment course. The SIMPLE study results in patients with severe disease may enable us to significantly increase the number of treatment courses using our remdesivir supply.

Capacity Expansion through External Manufacturing

We have supplemented our internal manufacturing with significant additional capacity from multiple manufacturing partners in North America, Europe and Asia. Through these efforts, we believe we have created a manufacturing network capable of producing large volumes of remdesivir at the fastest pace feasible. Looking ahead, we are building a geographically diverse consortium of pharmaceutical and chemical manufacturing companies to help us meet and exceed these production goals by expanding capacity for raw materials and production beyond what any company could do individually.

Efforts to Further Increase Supply

While cases of COVID-19 continue to increase, only a portion of patients experience severe symptoms that may make them appropriate candidates for treatment with remdesivir. Patients currently receiving remdesivir through clinical trials or expanded access are hospitalized and have moderate to severe manifestations of COVID-19, such as early respiratory failure. According to the World Health Organization, approximately 14% of patients with COVID-19 will experience severe manifestations of the disease that require hospitalization and supplemental oxygen, and 5% will require treatment in intensive care units. The potential benefits and risks of treatment with remdesivir for COVID-19 are not yet fully known.

Gilead is also studying a five-day course of treatment for COVID-19 in ongoing clinical studies. If a five-day dosing duration is shown to be safe and effective, this would increase the number of patients who could be treated with the current supply projections. Our researchers are also looking at the future potential for developing inhaled and potentially oral dosage forms of remdesivir to help alleviate the need for hospital administration of the drug.

We are doing everything we can to accelerate manufacturing timelines and quantities of remdesivir to meet the growing demand for emergency use of the medicine from around the world and for clinical trials to determine whether remdesivir is safe and effective for the treatment of COVID-19. In addition to multiple ongoing

clinical studies actively enrolling patients, we are implementing expanded access programs as quickly as possible to help the most critically ill patients around the world with our limited supply.

Ensuring the Authenticity of Remdesivir

Gilead is committed to patient safety and ensuring that people have accurate information about investigational remdesivir, including how it is accessed and administered. We are actively monitoring for fraudulent offers of illegitimate remdesivir to protect patients from products that might be dangerous and lead to serious and life-threatening harm.

Read the facts about genuine remdesivir.



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