Gilead has aggressively implemented a multipronged approach to scale up production and rapidly build supply of the investigational antiviral remdesivir. We will have invested more than $100 million in the manufacturing of remdesivir by the end of May in order to meet the supply needs for clinical trials and emergency treatment programs, early demand following any potential regulatory authorizations, and to secure raw materials for future product supply.

Our monthly spend is projected to grow over the course of the year as we prepare for even greater demand to support patient needs around the world, in the event of additional regulatory authorizations. To support our goal of producing 1 million treatment courses by year-end, we plan to invest several hundred million dollars, not inclusive of investments in infrastructure to manage a greatly expanded supply chain. In addition, we will begin investing even further as early as June 2020 to start the manufacturing process for product supply that will be released in 2021.

The production of remdesivir is time- and resource-intensive.

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. Manufacturing a drug like remdesivir at scale typically takes nine to 12 months. The procurement and production of raw materials and their conversion into active pharmaceutical ingredients (API) currently takes 150 days. Raw materials are processed into multiple intermediates, one step at a time, with some individual steps taking weeks to complete. Converting API into finished drug product that is released for distribution adds another 28 days to the overall manufacturing timeline. This complex manufacturing process for remdesivir impacts the ability to rapidly produce large quantities of drug supply in an emergency situation like the COVID-19 pandemic.

Complicating the manufacturing process is the challenge of scarce raw materials, with their own lengthy production time, and specialized manufacturing capabilities with limited global capacity. Many of the chemicals used to manufacture remdesivir are sourced from around the world – including France, Germany, Hungary, Ireland, Italy, Portugal, Canada, the United States, China and Japan – and some substances are typically not stocked in large quantities. Gilead’s scale-up of manufacturing for remdesivir will require a significant increase in global production of certain novel substances that are not readily available — in the case of one key excipient, this requires a multiple-fold increase in production over the current global supply. In addition, as an intravenous treatment, remdesivir must be produced in a facility with sterile drug product manufacturing capabilities, which limits the number of organizations capable of manufacturing the drug. Any disruption to the supply chain impacting these scarce raw materials and other manufacturing inputs could reduce the amount of remdesivir that could be produced and increase the time it takes to do so.

We have shortened the manufacturing timeline and proactively ramped up production.

Since January, we have worked to refine the manufacturing process for remdesivir and have substantially shortened the manufacturing lead time from raw materials through to finished product. The end-to-end manufacturing timeline is now six to eight months, as described above. We continue to work on optimizing the chemical synthesis processes to further accelerate product deliveries and volumes.

REMDESVIR IS AN INVESTIGATIONAL PRODUCT AND HAS NOT BEEN APPROVED ANYWHERE GLOBALLY. THE SAFETY AND EFFICACY OF REMDESVIR FOR ANY USE HAVE NOT BEEN DETERMINED.
In anticipation of the potential need for increased supply, Gilead worked early on, before any clinical trials had started for the treatment of COVID-19, to procure a steady flow of raw materials. We made this investment at risk to accelerate large-scale production of remdesivir once these materials become available in significant quantities.

Additional external manufacturing expands our capacity.

The ability to produce large quantities of remdesivir is dependent on an international supply chain. We have supplemented our internal manufacturing with additional capacity from multiple manufacturing partners in the United States, Denmark, France, Germany, Hungary, Ireland, Italy, Portugal, China and Japan. In addition to our own manufacturing, a significant amount of our drug product will be produced by our external partners as we scale up supply. Through these efforts, we believe we have created a manufacturing network capable of producing large volumes of remdesivir at the fastest pace feasible.

The manufacturing supply chain was initially scaled to periodically make small amounts of product for a compound in early development, and our inventory of remdesivir in early January was approximately 5,000 treatment courses. Today, Gilead has an inventory of more than 30,000 treatment courses of remdesivir, and by the end of May, we expect we will have produced more than 140,000 treatment courses – a nearly 30-fold increase in supply from the start of the year. Based on the investments we have made, we have set a goal to produce more than 500,000 cumulative treatment courses of remdesivir by October, more than 1 million cumulative treatment courses by December 2020 and several million treatment courses in 2021, if required. These treatment course estimates are based on a 10-day duration of therapy.

Looking ahead, we are building a geographically diverse consortium of pharmaceutical and chemical manufacturing companies to help us reach and exceed our manufacturing goals and go above and beyond what any company could do individually.

Meeting the potential global demand for remdesivir is dependent on an international supply chain.

No one country or region can manufacture remdesivir on its own and meet the level of supply required. The raw materials and substances required, and the production capabilities and capacity required, represent a diverse network of companies that are working together to meet the needs of patients around the world. Any disruption in this supply chain could ultimately reduce the amount of remdesivir that could be produced and increase the time it takes to do so.

Gilead’s manufacturing network for remdesivir includes external partners from all over the world.

**ASIA**  China: 23 // Japan: 4

**EUROPE**  Belgium: 1 // France: 2 // Germany: 3 // Hungary: 2 // Ireland: 1 // Italy: 2 // Portugal: 1 // Russia: 1

**NORTH AMERICA**  Mexico: 2 // United States: 14

We are in discussions with many other companies around the world to add even more partners across the supply chain. These external partners complement Gilead’s internal manufacturing efforts in the United States and Canada.