GILEAD
Creating Possible

Response to Médecins Sans Frontières

April 10, 2020

Jessica Burry
HIV/HCV Pharmacist
MSF Access Campaign

Dear Ms. Burry,

I am writing in response to the open letter sent to Gilead co-signed by Médecins Sans Frontières and a number of civil society organizations and individuals dated March 30.

Since the COVID-19 outbreak emerged early this year, Gilead has worked with the utmost speed, care and diligence to determine how we can best support patients around the world. We understand the significant interest in our investigational antiviral remdesivir* as a potential treatment for COVID-19 and the responsibility companies like Gilead have to contribute to public health. We know the decisions we make have significant implications and share your urgency in responding to this global public health crisis. In fact, we announced last week that we will provide the initial supply of remdesivir, should it receive regulatory authorization, free of cost. This equates to 1.5 million individual doses – enough supply to equal well over 140,000 treatment courses for patients.

We have a long legacy of making our medicines broadly available – today, an estimated 13 million people living with HIV in low-income countries are taking a Gilead-based regimen. This was made possible through our partnerships with low-cost manufacturing partners. We granted the first voluntary licenses for our HIV medications in 2006 and, in 2011, we were the first biopharmaceutical company to donate to the Medicines Patent Pool. Over the years, we have worked with our manufacturing partners to provide not only a license, but also the technology transfer and support to scale production. Our focus on providing access to medicines to people around the world has been unwavering. While the circumstances are different, it is this legacy that offers us insight into how we can provide remdesivir, should it receive regulatory authorization, during this pandemic.

We recognize that in moments of urgency all ideas need to be considered. As we have in the past, we are carefully evaluating licensing as one of many solutions that could enable a rapid increase in supply of remdesivir. Working with regulatory authorities worldwide, we recently transitioned from a compassionate use program to expanded access programs with the goal of ultimately reaching more patients and, to date, more than 1,700 people around the world have received remdesivir through these efforts. These programs are in addition to multiple ongoing international clinical trials.

Earlier this year, as the number of COVID-19 cases started to grow, we began to increase our production

*Remdesivir is an investigational product that has not been approved anywhere globally, and the safety and efficacy of remdesivir for the treatment of COVID-19 is not yet known.

of remdesivir. We made the decision to invest and scale up manufacturing because we felt it was critical to be ready – even as we continued and still continue to navigate a number of unknowns, including how long the outbreak might last and whether remdesivir will ultimately be proven safe and effective. From the outset it has been clear to us that this is not something we can do alone – and we've sought the partnership of the industry's best.

Remdesivir is difficult to make: The process is resource and time intensive, with some individual manufacturing steps taking weeks to complete. This complex process impacts the ability to rapidly produce large quantities of drug supply in an emergency situation like the COVID-19 pandemic. We have also supplemented our internal manufacturing with significant additional capacity from multiple manufacturing partners in North America, Europe and Asia.

We've shared more information about the development and supply of remdesivir on our website.

The human health crisis created by the COVID-19 pandemic is one of the most significant public health crises of our lifetimes and all of us at Gilead empathize with the families who have lost loved ones and are facing heartbreaking challenges. This is a moment to come together collaboratively as we work toward a shared goal: finding an answer to the question of whether remdesivir can play a role in helping to treat patients with COVID-19 and, if so, working together to bring it to the patients who need it with the greatest possible speed.

I can assure you, on behalf of everyone at Gilead, that we are actively considering every potential pathway to achieve this goal, including exploring with regulatory authorities and international organizations effective mechanisms to make remdesivir globally available and establishing an independent advisory committee to advise us on appropriate allocations. We are currently engaged in discussions with UNICEF, which as you are aware, is known for its rapid response in getting medicines and supplies to countries during emergency and humanitarian crises. As we've done with our medicines for HIV and viral hepatitis, we will pursue solutions that are collaborative and inclusive, with the aim of providing access to the greatest possible number of patients.

Thank you,
Brett Pletcher
EVP, Corporate Affairs & General Counsel
Gilead Sciences