



## **Gilead Sciences Statement on Request to Rescind Remdesivir Orphan Drug Designation**

Gilead has submitted a request to the U.S. Food and Drug Administration to rescind the orphan drug designation it was granted for the investigational antiviral remdesivir for the treatment of COVID-19 and is waiving all benefits that accompany the designation. Gilead is confident that it can maintain an expedited timeline in seeking regulatory review of remdesivir, without the orphan drug designation. Recent engagement with regulatory agencies has demonstrated that submissions and review relating to remdesivir for the treatment of COVID-19 are being expedited.

In early March, Gilead sought and was subsequently granted an orphan drug designation for the remdesivir as a potential treatment for COVID-19. Orphan drug designation is granted by the FDA in situations where the disease affects fewer than 200,000 patients in the United States.

Among the benefits of orphan drug designation, this status results in a waiver of the requirement to provide a pediatric study plan prior to the submission of a New Drug Application – a process that can take up to 210 days to review.

Gilead recognizes the urgent public health needs posed by the COVID-19 pandemic. The company is working to advance the development of remdesivir as quickly as possible, and will provide updates as they become available.

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