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Mylan secures DCGI approval for Remdesivir

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The drug will be launched under the brand name DESREM in India



Mylan N.V. has announced that the Drug Controller General of India (DCGI) has approved its remdesivir 100 mg/vial for restricted emergency use in India as part of the DCGI's accelerated approval process to address urgent, unmet needs amid the evolving coronavirus 2019 (COVID-19) pandemic.

The drug is approved for the treatment of suspected or laboratory confirmed incidences of COVID-19 in adults and children hospitalized with severe presentations of the disease.

The drug will be launched under the brand name DESREM™ in India and will be available to patients in July at a price of INR 4,800, which is more than 80% less than the price at which the branded version of this product will be available to governments in the developed world.

Mylan will manufacture remdesivir in India at its world-class injectables facilities, which also make product for the U.S. and have been inspected by the U.S. Food and Drug Administration (FDA) for compliance with good manufacturing practices.

The company continues to work extensively toward expanding emergency use access for patients in the 127 low- and middle-income countries where it is licensed by Gilead Sciences to do so, subject to reviews by national regulatory bodies and the Prequalification Program of the World Health Organization (WHO). The approval by DCGI in India represents the first for Mylan in these 127 markets.

Mylan President Rajiv Malik said: "Mylan and Gilead Sciences have partnered for many years to make high quality medicines available to people who need them and have made significant progress to reduce the incidence of infectious diseases, including HIV/AIDS, around the world. We commend Gilead for their continued leadership on this front, and also applaud and are proud to continue partnering with the DCGI for its ongoing efforts to accelerate access to critical medicine for patients with COVID-19 in India.

Malik continued: "Our approval is a significant milestone for Mylan, for the global public health community and, most importantly, for patients who are battling this pandemic. Developing DESREM™ and bringing it to patients in India with such unprecedented speed is a testament to the strength of our global operations and scientific capabilities and our commitment to serving patients who continue to rely on us during this time. We are proud to continue our work in support of public health in partnership with governments and other stakeholders as we work together in the fight against COVID-19."

Rakesh Bamzai, President, India and Emerging Markets, said: "The growing global threat of COVID-19 requires a commitment to action by everyone involved in public health. Mylan is cognizant of its responsibility in fighting this pandemic and will leverage its global resources and capabilities including R&D, regulatory, manufacturing and supply chain, while engaging with key stakeholders across the licensed territories to serve the patients in need and further its mission of creating better health for a better world."