Mylan Secures Regulatory Approval for Remdesivir Lyophilized Powder for Injection 100 mg/vial in India for Restricted Emergency Use in COVID-19 Patients

July 6, 2020

HERTFORDSHIRE, England and PITTSBURGH and BANGALORE, India, July 6, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today 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 inIndia 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**."**

Mylan previously announced a global collaboration agreement with Gilead Sciences for the commercialization of remdesivir in 127 low- and middle-income countries, including India. Mylan has a long-standing history of partnering with Gilead to tackle key public health issues in India and around the world, beginning with expanding access to high quality, affordable HIV/AIDS antiretrovirals and now extending its partnership to include COVID-19 treatments. Remdesivir is the tenth medicine licensed to Mylan by Gilead, who signed their first agreement in 2006 for the HIV medicine, tenofovir disoproxil fumarate.

As a leading global pharmaceutical company, Mylan is committed to continue doing its part in support of public health needs. As the situation around COVID-19 continues to evolve, Mylan's priorities remain protecting the health and safety of its workforce, continuing to produce critically needed medicines, deploying our resources and expertise in the fight against COVID-19 through potential prevention and treatment efforts, and supporting the communities in which we operate.

About Remdesivir
Remdesivir is an investigational new drug developed by Gilead Sciences. Interim results of two large Phase III clinical trials have demonstrated favourable outcomes with Remdesivir. Based on the results, USFDA granted emergency use authorization (EUA) of Remdesivir to treat hospitalized patients with severe COVID-19 in the U.S. In addition, it is recommended for compassionate use in Europe and recently received regulatory approval in Japan, Taiwan and Singapore.

About Mylan
Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high-quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time.

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