# Mylan to Supply Investigational Antiviral Remdesivir for the Potential Treatment of COVID-19

May 12, 2020

**Mylan and Gilead Sciences sign global collaboration agreement for the commercialization of remdesivir in 127 low- and middle-income countries**

HERTFORDSHIRE, England and PITTSBURGH, May 12, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced, as part of its ongoing efforts to support patients and public health needs during the COVID-19 pandemic, a global collaboration with Gilead Sciences to expand access to the investigational antiviral remdesivir for the potential treatment of COVID-19.

Under the terms of the license agreement signed with Gilead, Mylan has rights to manufacture and distribute remdesivir in 127 low- and middle-income countries, including India. The agreement is non-exclusive, allowing for multiple licensees to ensure extensive access to this treatment, once approved as safe and effective for COVID-19 patients.

Mylan CEO Heather Bresch said: "Mylan and Gilead have partnered for 15 years to fight infectious diseases like HIV and hepatitis C, reaching nearly 10 million patients in more than 100 countries with affordable medicine. We applaud Gilead's progress on remdesivir and are committed to continue deploying our resources and expertise in the fight against COVID-19 by applying our R&D and manufacturing capabilities to help expand access to this potential treatment option as it is further evaluated by regulatory authorities."

To ensure preparedness in this critical time of need, Mylan is confident it will be able to develop a bioequivalent version of remdesivir, including production of its own active pharmaceutical ingredient (API) and the finished dosage form (FDF) in sterile powder lyophilized vials for administration of the medicine by intravenous (IV) infusion. We will be in a position to provide product in the coming months, subject to reviews by national regulatory bodies and the Prequalification Program of the World Health Organization (WHO).

Mylan President Rajiv Malik said: "The unprecedented development timeline at Mylan is a direct reflection of the investments we've made to build a first-class, global research and manufacturing platform, including strong technical expertise in injectable dosage forms. As a world leader in the supply of antiretroviral drugs upon which approximately 40% of those being treated for HIV/AIDs depend, we also understand supply chain complexities that must be overcome in order to ensure that the products we manufacture are able to reach the patients who need them. Today's announcement is another example of how Mylan's unique global infrastructure and expertise empower other companies to expand their own reach by providing more patients with access to critical medicines worldwide."

Remdesivir is the tenth medicine licensed to Mylan by Gilead, who signed their first agreement in 2006 for the HIV medicine, tenofovir disoproxil fumarate. Mylan has since been at the forefront of increasing access to HIV and viral hepatitis treatments developed by Gilead, including bioequivalent forms of Atripla®, Sovaldi® and Descovy®, for which Mylan was the first licensee to achieve approval by the WHO's Prequalification Program or by the U.S. Food and Drug Administration (FDA) under the President's Emergency Plan for AIDS Relief (PEPFAR). Mylan supplies HIV treatments containing tenofovir to more than 8 million people each year and has reached 1 million patients with hepatitis C treatments containing sofosbuvir, also licensed from Gilead.

The growing global threat of COVID-19 requires a commitment to action by everyone involved in public health. Mylan takes its responsibility seriously and is committed to continuing to work with governments, partners, and others to identify areas of need where our global R&D, regulatory, manufacturing and supply chain expertise can be of service.

**About Remdesivir**
Remdesivir is an investigational new drug developed by Gilead Sciences. The treatment was recently granted emergency use authorization (EUA) to treat hospitalized COVID-19 patients in the U.S. In addition, it is recommended for compassionate use in Europe and recently received regulatory approval in Japan. Two global clinical trials conducted to date have demonstrated positive results, reducing the recovery time for patients with COVID-19, although the full efficacy and safety of the treatment are still under investigation.

**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. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

*Forward-Looking Statement*

This press release includes statements that constitute "forward-looking statements," including with regard to Mylan and Gilead Sciences signing a global collaboration agreement for the commercialization of remdesivir in 127 low- and middle-income countries; the agreement being non-exclusive, allowing for multiple licensees to ensure extensive access to this treatment, once approved as safe and effective for COVID-19 patients; Mylan being committed to continue deploying our resources and expertise in the fight against COVID-19 by applying our R&D and manufacturing capabilities to help expand access to this potential treatment option as it is further evaluated by regulatory authorities; Mylan being confident it will be able to develop

a bioequivalent version of remdesivir, including production of its own API and the finished dosage form (FDF) in sterile powder lyophilized vials for administration of the medicine by intravenous (IV) infusion; we will be in a position to provide product in the coming months, subject to reviews by national regulatory bodies and the Prequalification Program of the World Health Organization (WHO); today's announcement being another example of how Mylan's unique global infrastructure and expertise empower other companies to expand their own reach by providing more patients with access to critical medicines worldwide; the timing and outcome of regulatory approvals and the effectiveness and approval of potential treatments. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to the potential widespread and highly uncertain impact of public health outbreaks, epidemics and pandemics, such as the COVID-19 pandemic; any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.


View original content to download multimedia:http://www.prnewswire.com/news-releases/mylan-to-supply-investigational-antiviral-remdesivir-for-the-potential-treatment-of-covid-19-301058044.html

SOURCE Mylan N.V.

Christine Waller (Media), 724.514.1968; Melissa Trombetta (Investors), 724.514.1813