Mylan Ramps Up U.S. Manufacturing of Hydroxychloroquine Sulfate Tablets to Meet Potential COVID-19 Patient Needs

March 19, 2020

HERTFORDSHIRE, England and PITTSBURGH, March 19, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced its continued commitment to do its part in support of public health needs amidst the evolving COVID-19 pandemic. The company continues to focus its efforts on protecting our employees, producing critically needed medications, and turning our scientific and operational expertise towards identifying additional ways we may be able to assist in the massive prevention, diagnosis and treatment efforts needed to counter the spread of COVID-19.

For example, in the immediate term, Mylan has restarted production of hydroxychloroquine sulfate tablets at its West Virginia manufacturing facility in the U.S. to meet the potential for increased demand resulting from potential effectiveness of the product in treating COVID-19. Mylan's hydroxychloroquine sulfate tablets are approved by the U.S. Food and Drug Administration (FDA) for the treatment of malaria, lupus erythematosus and rheumatoid arthritis. Although the product is not currently approved for use in the treatment of COVID-19, it is listed by the World Health Organization as a drug under investigation for efficacy against the coronavirus[1]. The company is also taking steps to initiate production of this product outside the U.S. in the coming weeks. We look forward to working with governments and health authorities globally to ensure patient access to this medicine as and where needed.

Mylan expects to be in a position to begin supplying product by mid-April, and with the active pharmaceutical ingredient that we currently have available, will be able to ramp up manufacturing to provide 50 million tablets to potentially treat a total of more than 1.5 million patients. The potential use of this medicine for COVID-19 related treatment is pending additional FDA and other regulatory body guidance.

The growing global threat of COVID-19 requires a commitment 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 and manufacturing expertise and capacity can be of service.

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 growing 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 more than 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.

This press release includes statements that constitute "forward-looking statements," including with regard to the potential approval and/or use of hydroxychloroquine sulfate tablets in the treatment of COVID-19; that Mylan expects to be in a position to begin supplying product by the second week of April, and with the active pharmaceutical ingredient that we currently have available will be able to ramp up manufacturing to provide 50 million tablets to potentially treat a total of more than 1.5 million patients; that the potential use of this medicine for COVID-19 related treatment is pending additional FDA and other regulatory body guidance; and that Mylan is committed to continuing to work with governments, partners and others to identify areas of need where our global R&D, regulatory and manufacturing expertise and capacity can be of service. 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 impact of public health outbreaks 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.

[1] https://www.who.int/blueprint/priority-diseases/key-action/Table_of_therapeutics_Appendix_17022020.pdf?ua=1



View original content to download multimedia:http://www.prnewswire.com/news-releases/mylan-ramps-up-us-manufacturing-of-hydroxychloroquine-sulfate-tablets-to-meet-potential-covid-19-patient-needs-301027106.html

SOURCE Mylan N.V.

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