



Mylan Announces Additional Efforts to Support Response to the COVID-19 Pandemic by Voluntarily Waiving its Marketing Exclusivity in the U.S. for Lopinavir/Ritonavir to Help Ensure Wider Availability to Meet Potential COVID-19 Patient Needs

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HERTFORDSHIRE, England and PITTSBURGH, March 25, 2020 /PRNewswire/ -- [Mylan](#) (NASDAQ: MYL) today announced that, in its ongoing effort to support patients and public health needs in the current unprecedented circumstances surrounding the COVID-19 pandemic, Mylan has voluntarily waived its exclusive rights in the U.S. to distribute its generic version of Kaletra® (lopinavir/ritonavir) antiretroviral 100mg/25mg and 200mg/50mg tablets to help increase the available supply of the product should it prove effective in the treatment of coronavirus. By doing so, Mylan will enable other generic applicants to be eligible for FDA approval of their medicines for patients in the U.S., expanding access in the event that additional clinical studies or other evaluations conclude that the product may be effective in treating COVID-19.

Mylan was the first company to file a substantially complete abbreviated new drug application with the Food and Drug Administration (FDA) to bring a generic version of this product to market, entitling the company to a 180-day marketing exclusivity period upon final FDA approval, which is pending.

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 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 regulatory approvals, market exclusivity and the potential approval and/or use of generic Kaletra® (lopinavir/ritonavir) antiretroviral tablets in the treatment of COVID-19. 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 the COVID-19 pandemic; the timing or outcome of FDA review and approval; actions and decisions of healthcare and pharmaceutical regulators; changes in healthcare, pharmaceutical or other laws and regulations in the United States and abroad; 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.



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SOURCE Mylan N.V.

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