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Mylan Receives WHO Prequalification for Generic Sovaldi®

First Generic Prequalification for Sofosbuvir Tablets

HERTFORDSHIRE, England and PITTSBURGH, July 26, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL), a leading global pharmaceutical company, today announced receipt of approval from the World Health Organization Prequalification of Medicines Program (WHO PQ) of its application for Sofosbuvir Tablets, 400 mg, a generic version of Gilead Sciences' Sovaldi®. Sofosbuvir, a directly acting antiretroviral, will be available in developing countries to treat hepatitis C.



Mylan's Sofosbuvir Tablets, 400 mg, which are produced under license from Gilead Sciences, are the first generic version to be approved under the WHO PQ Program. With WHO PQ approval, international donors and purchasers, such as UNITAID and U.N. agencies, will be able to fund and procure the product, and other buyers can be assured of the product's quality, safety and efficacy.

"This marks another important step in Mylan's leadership to help fight infectious diseases around the world," commented Mylan President Rajiv Malik. "It also furthers our mission of increasing access to high quality, affordable medicines to patients, healthcare practitioners, governments and other stakeholders to help treat hepatitis C."

Worldwide, there are more than 70 million people living with chronic hepatitis C, which results in nearly 400,000 related deaths every year. (1) The WHO estimates that antiviral medication can cure more than 95% of chronic hepatitis C cases. (2)

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 50% of people being treated for HIV/AIDS in the developing world 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.

(1, 2) <http://www.who.int/mediacentre/factsheets/fs164/en/>

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