



Mylan Launches First Generic for Adcirca® Tablets

August 13, 2018

**- Tadalafil is indicated in the treatment of pulmonary arterial hypertension to improve exercise ability -
- Mylan awarded 180 days of marketing exclusivity -**

HERTFORDSHIRE, England and PITTSBURGH, Aug. 13, 2018 /PRNewswire/ -- Global pharmaceutical company [Mylan N.V.](#) (NASDAQ: MYL) today announced the U.S. launch of Tadalafil Tablets USP, 20 mg, the first generic version of the reference listed drug, Eli Lilly and Company's Adcirca®.

Mylan Pharmaceuticals received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) and was awarded 180 days of marketing exclusivity for this product, which is indicated for the treatment of pulmonary arterial hypertension to improve exercise ability.

"Mylan has a strong history of leading the way in creating important access to generic medicines, and we're excited to continue that tradition by offering the first generic to Adcirca® Tablets," said Mylan CEO Heather Bresch. "Mylan offers more than 650 products in the U.S., and the addition of Tadalafil Tablets strengthens our cardiovascular portfolio and commitment to these patients."

U.S. sales for Tadalafil Tablets USP, 20 mg, were approximately \$510 million for the 12 months ending May 31, 2018, according to IQVIA.

Currently, Mylan has 192 ANDAs pending FDA approval representing approximately \$88.3 billion in annual brand sales, according to IQVIA. Forty-four of these pending ANDAs are potential first-to-file opportunities, representing \$44.9 billion in annual brand sales, for the 12 months ending December 31, 2017, according to IQVIA.

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 more than 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](#).



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SOURCE Mylan N.V.

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