



June 2, 2016

Mylan Launches Generic Rythmol® Sustained-Release Capsules

HERTFORDSHIRE, England and PITTSBURGH, June 2, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Propafenone Hydrochloride Extended-Release Capsules USP, 225 mg, 325 mg, 425 mg, a generic version of GlaxoSmithKline's Rythmol® SR. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is indicated to prolong the time to recurrence of symptomatic atrial fibrillation (AF) in patients with episodic (most likely paroxysmal or persistent) AF who do not have structural heart disease.(1)



Propafenone Hydrochloride Extended-Release Capsules USP, 225 mg, 325 mg, 425 mg, had U.S. sales of approximately \$100.5 million for the 12 months ending March 31, 2016, according to IMS Health.

Currently, Mylan has 254 ANDAs pending FDA approval representing \$108.3 billion in annual brand sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing \$37.2 billion in annual brand sales, for the 12 months ending December 31, 2015, according to IMS Health.

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 1,400 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in approximately 165 countries and territories. Our global R&D and manufacturing platform includes more than 50 facilities, and we are one of the world's largest producers of active pharmaceutical ingredients. Every member of our nearly 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) Antiarrhythmic agents should generally be avoided in patients with non-life-threatening ventricular arrhythmias, even if the patients are experiencing unpleasant, but not life-threatening, symptoms or signs.

Logo - <http://photos.prnewswire.com/prnh/20140423/77793>

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/mylan-launches-generic-rythmol-sustained-release-capsules-300278388.html>

SOURCE Mylan N.V.

News Provided by Acquire Media