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Mylan Launches First Generics of Benicar® and Benicar HCT® Tablets

HERTFORDSHIRE, England and PITTSBURGH, Oct. 26, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launches of the first generic versions of Daiichi Sankyo's Benicar® and Benicar HCT®, Olmesartan Medoxomil Tablets, 5 mg, 20 mg and 40 mg, and Olmesartan Medoxomil and Hydrochlorothiazide Tablets, 20 mg/12.5 mg, 40 mg/12.5 mg, and 40 mg/25 mg, respectively. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Applications (ANDA) for these products.



Olmesartan Medoxomil Tablets are indicated for the treatment of hypertension, along or with other antihypertensive agents, to lower blood pressure. Olmesartan Medoxomil and Hydrochlorothiazide Tablets are indicated for the treatment of hypertension to lower blood pressure, and are not indicated for the initial therapy of hypertension. (1)

Olmesartan Medoxomil Tablets, 5 mg, 20 mg and 40 mg, had U.S. sales of approximately \$1 billion for the 12 months ending August 31, 2016, according to IMS Health. Olmesartan Medoxomil and Hydrochlorothiazide Tablets, 20 mg/12.5 mg, 40 mg/12.5 mg, and 40 mg/25 mg had U.S. sales of approximately \$805 million during that same time.

Currently, Mylan has 237 ANDAs pending FDA approval representing \$94.4 billion in annual brand sales, according to IMS Health. Forty-one of these pending ANDAs are potential first-to-file opportunities, representing \$32.5 billion in annual brand sales, for the 12 months ending June 30, 2016, 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 2,700 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS worldwide depend. We market our products in more than 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 more than 40,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

(1) When pregnancy is detected, discontinue as soon as possible. Drugs that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

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