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Mylan Launches First Generic Maxalt MLT® Tablets

- Company also launching immediate-release version Maxalt® Tablets -

PITTSBURGH, Jan. 2, 2013 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Pharmaceuticals has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Applications (ANDA) for Rizatriptan Benzoate Orally Disintegrating Tablets, 5 mg (base) and 10 mg (base), and Rizatriptan Benzoate Tablets, 5 mg (base) and 10 mg (base). These products are the generic versions of Merck's Maxalt MLT® Tablets and Maxalt® Tablets, respectively, and are indicated for the acute treatment of migraine with or without aura in adults.

Mylan was the first company to have filed a substantially complete ANDA containing a Paragraph IV certification for Rizatriptan Benzoate Orally Disintegrating Tablets, 5 mg (base) and 10 mg (base), and was awarded 180 days of marketing exclusivity.

Mylan CEO Heather Bresch commented: "Mylan's immediate launch of the first generic Rizatriptan Benzoate Orally Disintegrating Tablets, 5 mg (base) and 10 mg (base), and the company's simultaneous launch of Rizatriptan Benzoate Tablets, 5 mg (base) and 10 mg (base), further demonstrates our commitment to continue expanding access to high quality medicines for patients who need them in the U.S. and around the world. We look forward to continue growing our portfolio of more than 1,100 generic pharmaceutical products to further support this cause."

Rizatriptan Benzoate Orally Disintegrating Tablets, 5 mg (base) and 10 mg (base), had U.S. sales of approximately \$262.5 million for the 12 months ending Sept. 30, 2012, according to IMS Health, and Rizatriptan Benzoate Tablets, 5 mg (base) and 10 mg (base), had U.S. sales of approximately \$344.7 million for the same period. Mylan is shipping the orally disintegrating and immediate-release versions of this product immediately.

Currently, Mylan has 183 ANDAs pending FDA approval representing \$79.9 billion in annual sales, according to IMS Health. Thirty-four of these pending ANDAs are potential first-to-file opportunities, representing \$20.8 billion in annual brand sales, for the 12 months ending June 30, 2012, according to IMS Health.

Mylan is a global pharmaceutical company committed to setting new standards in health care. 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 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 1,100 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately one-third of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 150 countries and territories. Our workforce of more than 18,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. mylan.com

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