



August 28, 2014

Mylan's ANDA for Three Times Per Week Generic Copaxone® 40 mg/mL Accepted for Filing by FDA

PITTSBURGH, Aug. 28, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its abbreviated new drug application (ANDA) for a three times per week Glatiramer Acetate Injection 40 mg/mL has been accepted for filing by the U.S. Food and Drug Administration (FDA). This product is the generic version of Teva's Copaxone® 40 mg/mL, which is indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS).



Mylan believes it is one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for this product and expects to be eligible for 180 days of marketing exclusivity in the U.S. upon final FDA approval.

Copaxone 40 mg/mL had U.S. sales of approximately \$411.5 million for the 12 months ending June 30, 2014, according to IMS Health.

Currently, Mylan has 294 ANDAs pending FDA approval representing \$105.7 billion in annual brand sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing \$25.0 billion in annual brand sales, for the 12 months ending Dec. 31, 2013, according to IMS Health.

This press release includes statements that constitute "forward-looking statements," including with regard to sales of products. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in legal and regulatory processes; and the other risks detailed in the company's filings with the Securities and Exchange Commission. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.

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 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 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% 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 140 countries and territories. Our workforce of more than 20,000 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

Copaxone® is a registered trademark of Teva Pharmaceutical Industries Ltd.

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

SOURCE Mylan Inc.

News Provided by Acquire Media