July 25, 2013

Mylan Announces STALEVO® Settlement Agreement

PITTSBURGH, July 25, 2013 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that Mylan Pharmaceuticals Inc. ("Mylan") and Orion Corporation have entered into a settlement and license agreement settling the parties litigation in connection with Mylan's filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Carbidopa/Levodopa/Entacapone Tablets, 12.5 mg/50 mg/200 mg, 18.75 mg/75 mg/200 mg, 25 mg/100 mg/200 mg, 31.25 mg/125 mg/200 mg, 37.5 mg/150 mg/200 mg, and 50 mg/200 mg/200 mg. This product is the generic version of STALEVO®, which is indicated to treat patients with idiopathic Parkinson's disease to substitute (with equivalent strength of each of the three components) for immediate-release Carbidopa/Levodopa and Entacapone previously administered as individual products.

Under the terms of the settlement and license agreement, Mylan may launch an authorized generic version of STALEVO immediately and its own ANDA product upon receiving final FDA approval. Pursuant to the agreement, the parties pending litigation will be dismissed. All other terms and conditions of the settlement and license agreement are confidential, and the agreement itself is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

For the 12 months ending March 31, 2013, STALEVO had U.S. sales of approximately $138.6 million, according to IMS Health.

Currently, Mylan has 174 ANDAs pending FDA approval representing $83.2 billion in annual sales, according to IMS Health. Thirty-seven of these pending ANDAs are potential first-to-file opportunities, representing $23 billion in annual brand sales, for the 12 months ending Dec. 31, 2012, according to IMS Health.

This press release includes statements that constitute "forward-looking statements," including with regard to the settlement of the litigation and sales of the product. 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: any legal or regulatory challenges to the settlement; 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 approximately 1,100 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

SOURCE Mylan Inc.