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Mylan Launches First Generic Version of Orapred ODT®

- Company awarded 180 days of marketing exclusivity -

PITTSBURGH, Dec. 11, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced the U.S. launch of its Prednisolone Sodium Phosphate Orally Disintegrating Tablets, 10 mg, 15 mg, and 30 mg. This product is the first generic version of Shionogi's Orapred ODT®. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Prednisolone Sodium Phosphate Orally Disintegrating Tablets, 10 mg, 15 mg, and 30 mg, and was awarded 180 days of generic drug marketing exclusivity. This product is indicated as an anti-inflammatory or immunosuppressive agent for certain conditions; and also for the treatment of certain endocrine conditions, and for palliation of certain neoplastic conditions.

Prednisolone Sodium Phosphate Orally Disintegrating Tablets, 10 mg, 15 mg, and 30 mg, had U.S. sales of approximately \$19.9 million for the 12 months ending September 30, 2014, according to IMS Health.

Currently, Mylan has 286 ANDAs pending FDA approval representing \$111.6 billion in annual brand sales, according to IMS Health. Forty-five of these pending ANDAs are potential first-to-file opportunities, representing \$29.5 billion in annual brand sales, for the 12 months ending June 30, 2014, 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 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. Learn more at mylan.com.

To view the original version on PR Newswire, visit: http://www.prnewswire.com/news-releases/mylan-launches-first-generic-version-of-orapred-odt-300008426.html

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