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Mylan Confirms First-to-File Patent Challenge Relating to DELZICOL®

HERTFORDSHIRE, England and PITTSBURGH, Nov. 19, 2015 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today confirmed that its subsidiaries Mylan Pharmaceuticals Inc., Mylan Laboratories Limited and Mylan Inc., have been sued by Warner Chilcott (US), LLC, Warner Chilcott Company, LLC and Qualicaps Co. Ltd. in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Mesalamine Delayed-release Capsules, 400 mg. This product is the generic version of DELZICOL®, which is indicated for the (1) treatment of mildly to moderately active ulcerative colitis in patients 5 years of age and older and (2) maintenance of remission of ulcerative colitis in adults.

Mylan believes it is the first or 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 upon final FDA approval. The plaintiffs have filed a lawsuit against Mylan in the United States District Court for the Eastern District of Texas.

For the 12 months ending Sept. 30, 2015, DELZICOL had U.S. sales of approximately $180 million, according to IMS Health.

Currently, Mylan has 253 ANDAs pending FDA approval representing $100.8 billion in annual brand sales, according to IMS Health. Fifty of these pending ANDAs are potential first-to-file opportunities, representing $36.1 billion in annual brand sales, for the 12 months ending June 30, 2015, 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 around 1,400 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which nearly 50% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in about 145 countries and territories. Our workforce of approximately 30,000 people is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

This press release includes statements that constitute "forward-looking statements," including with regard to Mylan's belief that it is one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for the product and that it expects to be eligible for 180 days of marketing exclusivity in the U.S. upon final FDA approval and pending litigation. 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: the use of legal, regulatory and legislative strategies by competitors or other third parties to delay or prevent our introduction of new products; actions taken by regulatory and governmental agencies with respect to our or our competitors' current or future products; success of clinical trials and our ability to execute on new product opportunities; other risks inherent in legal and regulatory processes, uncertainties and matters beyond the control of management; 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.

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