Mylan Confirms First-to-File Patent Challenge Relating to Actoplus Met® XR Tablets

Expects to qualify for 180 days of marketing exclusivity

PITTSBURGH, Jan. 9, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that the company has been sued by Takeda Pharmaceutical Company, Watson Pharmaceuticals and Andrx Labs in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Pioglitazone Hydrochloride and Extended-release Metformin Hydrochloride tablets, 15 mg/1000 mg and 30 mg/1000 mg. This product is the generic version of Actoplus Met® XR, which is indicated to improve glycemic control in adults with type 2 diabetes mellitus.

Mylan believes it is the first company to have filed a substantially complete ANDA containing a Paragraph IV certification for all strengths and expects to qualify for 180 days of marketing exclusivity upon final FDA approval. The plaintiffs filed the lawsuit in the U.S. District Court for the Southern District of New York.

For the 12 months ending Sept. 30, 2011, Actoplus Met® XR had U.S. sales of approximately $13.9 million for the 15 mg/1000 mg strength product and $7.5 million for the 30 mg/1000 mg product, according to IMS Health.

Currently, Mylan has 170 ANDAs pending FDA approval representing $98.4 billion in annual sales, according to IMS Health. Forty-two of these pending ANDAs are potential first-to-file opportunities, representing $26.8 billion in annual brand sales, for the 12 months ending June 30, 2011, according to IMS Health.

This press release includes statements that constitute "forward-looking statements," including with regard to the expected first-to-file status 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 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 Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 150 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios supported by a robust product pipeline; operates one of the world's largest active pharmaceutical ingredient manufacturers; and runs a specialty business focused on respiratory, allergy and psychiatric therapies. For more information about Mylan, please visit www.mylan.com. For more information about generic drugs, please visit www.ChoosingGenerics.com.

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