Mylan Announces First-to-File Opportunity Settlement Agreements for Actoplus Met(R) and Actos(R)

PITTSBURGH, March 16, 2010 /PRNewswire via COMTEX News Network/ -- Mylan Inc. (Nasdaq: MYL) today announced that it has entered into settlement agreements with Takeda Pharmaceutical Co. related to two treatments for type 2 diabetes: Actoplus Met(R), 15 mg/500 mg and 15 mg/850 mg, known generically as Pioglitazone Hydrochloride (HCl) and Metformin HCl Tablets, and Actos(R), 15 mg, 30 mg and 45 mg, known generically as Pioglitazone HCl Tablets.

Actoplus Met

Mylan subsidiary Mylan Pharmaceuticals Inc. was the first company to submit a substantially complete Abbreviated New Drug Application (ANDA) containing a Paragraph IV certification to the U.S. Food and Drug Administration (FDA) for Actoplus Met and believes it will be eligible for 180 days of marketing exclusivity upon commercial marketing of the product, as provided under the provisions of the 1984 Hatch Waxman Act.

Pursuant to the settlement agreement, Mylan will have the right to market Pioglitazone HCl and Metformin HCl in the U.S. on Dec. 14, 2012, or earlier, under certain circumstances. Actoplus Met had 2009 U.S. sales of $459 million, according to IMS Health.

Actos

Mylan Pharmaceuticals also was one of the first companies to submit a substantially complete ANDA containing a Paragraph IV certification to the FDA for Actos and believes it will be eligible for 180 days of shared marketing exclusivity upon commercial marketing of the product. Pursuant to the settlement agreement, Mylan will have the right to market Pioglitazone HCl in the U.S. on Aug. 17, 2012, or earlier, under certain circumstances. Actos had 2009 U.S. sales of $3.4 billion, according to IMS Health.

Additional details of both agreements remain confidential and remain subject to review by the U.S. Department of Justice and the Federal Trade Commission.

Currently, Mylan has 142 ANDAs pending U.S. Food and Drug Administration approval representing $93.8 billion in annual brand sales; 40 of these pending ANDAs are potential first-to-file opportunities, representing $20 billion in annual brand sales for the 12 months ending Dec. 31, 2010, according to IMS Health.

Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 140 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, please visit www.mylan.com.

This press release includes statements that constitute "forward-looking statements," including with regard to the settlement and marketing 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 periodic 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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