Mylan Announces Settlement Agreement Related to Vfend(R) First-to-File Opportunity

PITTSBURGH, Oct 14, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Mylan Inc. (Nasdaq: MYL) today announced that the company's Mylan Pharmaceuticals and Matrix Laboratories subsidiaries entered into a settlement and license agreement with Pfizer Inc. relating to Voriconazole Tablets, 50 mg and 200 mg, the generic version of Pfizer's Vfend(R) Tablets, a triazole antifungal agent.

Mylan's Matrix 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) and therefore 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 agreement, Mylan will have the right to market Voriconazole Tablets in the U.S. in the first quarter of 2011. Additional details of the agreement with Pfizer remain confidential; the agreement is subject to the review by the U.S. Department of Justice and the Federal Trade Commission.

Voriconazole Tablets, 50 mg and 200 mg, had U.S. sales of $164 million for the 12 months ending June 30, according to IMS Health. Currently, Mylan has 121 ANDAs pending FDA approval representing $85.7 billion in annual brand sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing $17.9 billion in annual brand sales, according to IMS Health.

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.

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 the world's third largest active pharmaceutical ingredient manufacturer; and runs a specialty business focused on respiratory and allergy therapies. For more information, please visit www.mylan.com.

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