



Mylan Confirms First-to-File Patent Challenge Relating to Orapred ODT®

Expects to qualify for 180 days of marketing exclusivity for multiple strengths

PITTSBURGH, Dec. 17, 2010 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that the company and its subsidiary Mylan Pharmaceuticals Inc. have been sued by Shionogi Pharma Inc. and CIMA LABS INC. in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Prednisolone Sodium Phosphate Orally Disintegrating Tablets, 10 mg, 15 mg and 30 mg. This product is the generic version of Orapred ODT®, a corticosteroid indicated as an anti-inflammatory or immunosuppressive agent for the treatment of certain endocrine conditions and for palliation of certain neoplastic conditions.

Mylan believes it is the first company to have filed a substantially complete ANDA containing a Paragraph IV certification for the 10 mg, 15 mg and 30 mg strengths and expects to qualify for 180 days of marketing exclusivity upon final FDA approval. Shionogi Pharma and CIMA LABS filed the lawsuit in the U.S. District Court for the District of Delaware.

Orapred ODT had U.S. sales of approximately \$28 million for the 12 months ending Sept. 30, 2010, according to IMS Health. Currently, Mylan has 164 ANDAs pending FDA approval representing \$98.9 billion in annual sales, according to IMS Health. Forty-five of these pending ANDAs are potential first-to-file opportunities, representing \$24 billion in annual brand sales, for the 12 months ending June 30, 2010, 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 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.

SOURCE Mylan Inc.

News Provided by Acquire Media