Mylan Confirms First-to-File Patent Challenge Relating to Caduet(R)

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

PITTSBURGH, Feb 04, 2010 /PRNewswire via COMTEX News Network/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that it was sued by Pfizer in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Amlodipine Besylate and Atorvastatin Calcium Tablets 2.5/10 mg, 2.5/20 mg, 2.5/40 mg, 5/10 mg, 5/20 mg, 5/40 mg, 5/80 mg, 10/10 mg, 10/20 mg, 10/40 and 10/80 mg. This product is the generic version of Caduet(R) Tablets, which combine the long-acting calcium channel blocker amlodipine besylate with the synthetic lipid-lowering agent atorvastatin calcium.

Mylan believes it is the first company to have filed a substantially complete ANDA containing a Paragraph IV certification for the 2.5/10 mg, 2.5/20 mg, 2.5/40 mg and 10/40 mg strengths and expects to qualify for 180 days of marketing exclusivity upon final FDA approval. Pfizer filed the lawsuit in the U.S. District Court for the District of Delaware.

Caduet Tablets had approximately $65.6 million in sales for the 2.5/10 mg, 2.5/20 mg, 2.5/40 mg and 10/40 mg strengths for the twelve months ending Dec. 31, 2009, according to IMS Health. Currently, Mylan has 142 ANDAs pending FDA approval representing $87.5 billion in annual brand sales, according to IMS. Forty of these pending ANDAs are potential first-to-file opportunities, representing $19.6 billion in annual brand sales, according to IMS.

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.

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