Mylan Remains the Only Approved ANDA for All Strengths of Amlodipine Besylate Tablets

PITTSBURGH, April 30 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that the U.S. District Court for the District of Columbia issued a decision denying all requests for preliminary injunction related to Amlodipine Besylate Tablets and supporting the U.S. Food and Drug Administration's (FDA) position concerning Mylan's current status as the only approved ANDA for all strengths of this product. In the decision, the District Court confirmed the position taken by the FDA that all of the unapproved amlodipine besylate ANDAs are currently blocked from approval by pediatric exclusivity.

Mylan received final FDA approval for all strengths of Amlodipine Besylate Tablets on October 4, 2005, and commercially launched all strengths on March 23, 2007, after the U.S. Court of Appeals for the Federal Circuit in Washington ruled that claims 1-3 of the '303 patent were invalid. Amlodipine Besylate Tablets are the generic version of Pfizer's Norvasc® Tablets, which had U.S. sales of approximately $2.7 billion for the 12-month period ending Dec. 31, 2006, according to IMS Health.

Mylan Laboratories Inc. is a leading pharmaceutical company with three principal subsidiaries, Mylan Pharmaceuticals Inc., Mylan Technologies Inc. and UDL Laboratories Inc., and a controlling interest in Matrix Laboratories Limited, India. Mylan develops, licenses, manufactures, markets and distributes an extensive line of generic and proprietary products.

This press release includes statements that constitute "forward-looking statements," including with regard to Amlodipine Besylate Tablets 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 proceedings; 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.

SOURCE Mylan Laboratories Inc.

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