U.S. District Court Grants Extension for Consideration of Amlodipine Besylate Exclusivity

PITTSBURGH, April 10 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that the U.S. District Court for the District of Columbia has extended the deadlines pertaining to Mylan's request for a temporary restraining order in its lawsuit seeking to stop the U.S. Food and Drug Administration (FDA) from approving any other Amlodipine Besylate abbreviated new drug applications (ANDAs). At the request of the FDA, the court extended the deadlines in its previous order by one week so that the FDA is now enjoined from taking final agency action from April 18th, the date the FDA will notify the parties and the court of its position, until April 20th at 5:00 p.m. In its Motion to Alter Schedule, the FDA stated that it needs more time to review and respond in a meaningful manner to the numerous comments it has received. As previously disclosed, Mylan triggered its 180-day exclusivity period for all strengths of Amlodipine Besylate when it commercially launched the product on March 23rd. In addition, Mylan believes that it has further protection for its current exclusivity based on the pediatric exclusivity previously granted to Pfizer on the '303 patent which serves to block any additional approvals until September 25, 2007, the end of the pediatric exclusivity period. When the '303 patent expired, several valid claims remained, although they were not asserted against Mylan at trial.

About Mylan Laboratories

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 the launch of Amlodipine Besylate Tablets, pediatric exclusivity and the duration of market exclusivity. 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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