FDA Confirms Mylan's Status as the Only Approved ANDA for all Strengths of Amlodipine Besylate Tablets

PITTSBURGH, April 18 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that the U.S. Food and Drug Administration (FDA) has confirmed Mylan's current status as the only approved ANDA for all strengths of Amlodipine Besylate Tablets. The FDA notified Mylan and all amlodipine besylate ANDA applicants that all of the unapproved amlodipine besylate ANDAs are currently blocked from approval by pediatric exclusivity and if the mandate from the March 21 appellate court decision related to the validity of the amlodipine besylate patent does not issue before September 25, 2007, "Pfizer and Mylan will have no additional competition during the interim period and thus will obtain the full benefit that could be derived under pediatric and 180-day marketing exclusivity."

The FDA further stated that in the event an appellate court mandate is issued prior to September 25, the only ANDA eligible for approval during that period will be from Apotex because of the favorable court decision in the Pfizer case. Mylan will continue to assert that even Apotex should either be blocked by Mylan's 180-day exclusivity or not be approved during the pediatric exclusivity period based on multiple prior FDA rulings.

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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