Mylan Announces Final Approval for Amlodipine Besylate Tablets

FDA Confirms that Mylan Has 180 Days of Generic Exclusivity On All Strengths of $2.5 Billion Product -

PITTSBURGH, Pa., Oct. 4 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that Mylan Pharmaceuticals Inc. has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Amlodipine Besylate Tablets, 2.5 mg (base), 5 mg (base) and 10 mg (base). Amlodipine Besylate Tablets are the generic version of Pfizer's Norvasc® Tablets, which had U.S. sales of approximately $2.5 billion for the 12-month period ended June 30, 2005, according to IMS Health.

The FDA has confirmed that Mylan was the first generic company to file on all strengths of Norvasc® Tablets and is therefore eligible for 180 days of market exclusivity. The FDA has indicated that the exclusivity will begin to run from the earlier of the commercial launch of the Mylan product or a final court decision concerning the pending litigation between Pfizer and Mylan.

Mylan Laboratories Inc. is a leading pharmaceutical company with three principal subsidiaries, Mylan Pharmaceuticals Inc., Mylan Technologies Inc. and UDL Laboratories, Inc., that develop, license, manufacture, market and distribute an extensive line of generic and proprietary products.

For more information about Mylan, visit http://www.mylan.com.

This press release includes statements that constitute "forward-looking statements," including with regard to the launch of Amlodipine Besylate Tablets and 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.

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10/04/2005
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