FDA Extends PDUFA Action Date for Nebivolol Tablets to May 31, 2005

PITTSBURGH, Pa., Feb 25, 2005 /PRNewswire-FirstCall via COMTEX/ -- Mylan Laboratories Inc. (NYSE: MYL) announced today that its branded subsidiary, Mylan Bertek Pharmaceuticals, was notified by the U.S. Food and Drug Administration (FDA) on February 24, 2005, that the FDA has extended the original 10-month Prescription Drug User Fee Act (PDUFA) deadline for the completion of its review of the Company's New Drug Application (NDA) for Nebivolol, which is under review for the treatment of hypertension. The original action date for the Nebivolol NDA was February 28, 2005.

The extension stems from Mylan Bertek's recent submission, at the FDA's request, of an additional presentation of already-submitted data from the Nebivolol NDA. FDA regulations require that any PDUFA extension be three months, putting the new action date at May 31, 2005. Based upon discussions with the FDA, Mylan believes that it is possible the Agency may complete its final review before the new action date.

"Mylan is continuing to work closely with the FDA to assist them in the completion of their review of the Nebivolol application in a timely manner," said John O'Donnell, Ph.D., Chief Scientific Officer for Mylan Laboratories. "We are committed to an expeditious review and moving forward with the approval process."

Nebivolol, a new generation beta blocker that Mylan believes to have a unique profile, is under review for the treatment of hypertension. The NDA is based on data from more than 2,000 patients enrolled in Mylan Bertek clinical trials that evaluated the efficacy and safety of Nebivolol in lowering blood pressure in hypertensive patients regardless of age, race or gender when administered once daily. In vitro studies have demonstrated that Nebivolol is a highly beta-1 selective (cardioselective) blocker, which also increases nitric oxide levels. In clinical trials Nebivolol was well tolerated with an incidence of adverse events similar to that of placebo.

Mylan licensed the U.S. and Canadian rights to Nebivolol from Janssen Pharmaceutica N.V. in 2001. Nebivolol is already registered and successfully marketed in more than 45 other countries outside of North America.

Mylan Laboratories Inc. is a leading pharmaceutical company with four subsidiaries, Mylan Pharmaceuticals Inc., Mylan Technologies Inc., UDL Laboratories, Inc. and Mylan Bertek Pharmaceuticals 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 timing of the completion of the FDA's review and approval process, as well as Nebivolol's effectiveness and prospects. 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: an unfavorable ruling by the FDA or other unexpected regulatory delays; the risk that the product will not receive marketing approval or that it may not ultimately prove to be successful as an important therapy for hypertensive patients; uncertainties regarding market acceptance of and demand for the product; 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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