Mylan's NDA for Nebivolol Accepted for FDA Review

PITTSBURGH, July 1 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) announced today that the U.S. Food and Drug Administration (FDA) has accepted for filing its branded product subsidiary's, Mylan Bertek Pharmaceuticals Inc. (Mylan Bertek), New Drug Application (NDA) for nebivolol, for which the company is seeking approval for use in the management of hypertension.

"Based on the clinical trial data to date, we believe that nebivolol shows great promise as a valuable treatment for hypertension," stated Mylan Vice Chairman and CEO, Robert J. Coury. "Now that our nebivolol submission has been accepted by the FDA, we are excited to begin the review and approval process, and look forward to the addition of this exciting proprietary product to our growing brand franchise."

As previously stated, the application is based on data from more than 2,000 patients enrolled in clinical trials to demonstrate 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 Bertek filed its NDA with the FDA April 28, 2004 and the FDA has provided an action date of February 28, 2005.

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.

This press release includes statements that constitute "forward-looking statements", including with regard to nebivolol and its effectiveness, approval 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: risks 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; unexpected regulatory delays; 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.

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07/01/2004
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