Mylan Submits New Drug Application for Nebivolol

PITTSBURGH, May 5 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) announced today that its branded products subsidiary, Bertek Pharmaceuticals Inc., has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for nebivolol for use in the management of hypertension.

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 increasesnitric oxide levels. In clinical trials nebivolol was well tolerated with an incidence of adverse events similar to that of placebo.

Hypertension (high blood pressure) is a significant health risk affecting more than 50 million Americans(1), and there is a 90% residual lifetime risk of developing hypertension in persons who reach the age of 65.(2)

Mylan Vice Chairman and CEO, Robert J. Coury stated, "We are committed to developing new and improvedtherapeutic options, and are very excited that nebivolol, when approved, will be a valuable addition to the current treatment regimen for hypertension."

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 Bertek Pharmaceuticals Inc., that develop, manufacture and market 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.

REFERENCES

(1) American Heart Association, Heart and Stroke Statistical Update, 2004.

(2) JAMA 2002;287(8):1003-10

SOURCE Mylan Laboratories Inc.
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/CONTACT: Heather Bresch, Media, +1-724-514-1800, or Kris King, Investor, +1-724-514-1800, both of Mylan Laboratories Inc./
(MYL)

CO: Mylan Laboratories Inc.
ST: Pennsylvania
IN: BIO HEA MTC
SU: PDT

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