Mylan Laboratories Receives Approvable Letter For Its Next Generation Beta-Blocker Nebivolol

PITTSBURGH, June 1, 2005 /PRNewswire-FirstCall via COMTEX/ -- Mylan Laboratories Inc. (NYSE: MYL) announced today that its branded subsidiary, Mylan Bertek Pharmaceuticals, received an approvable letter from the U.S. Food and Drug Administration (FDA) on its New Drug Application (NDA) for nebivolol, which is under review for the treatment for hypertension. The NDA for nebivolol was submitted on April 30, 2004.

Robert J. Coury, Vice Chairman and Chief Executive Officer for Mylan Laboratories stated, "This is obviously an extremely important milestone for Mylan and its shareholders and is the direct result of the hard work and commitment of our employees. Nebivolol is a valuable asset to our organization and we look forward to continuing to work diligently with the FDA to gain final approval. We also look forward to providing additional information on our plans for this next generation beta-blocker as part of our investor presentation on June 14."

Final approval of nebivolol is contingent upon successfully satisfying additional FDA requirements regarding certain aspects of the pre-clinical data and finalization of the labeling. The pre-clinical data submitted in the NDA was based upon studies previously conducted by Janssen Pharmaceutica N.V. Belgium (currently Johnson & Johnson Pharmaceutical Research and Development Beerse), the company from whom Mylan licensed the product. Currently Mylan is conducting a pre-clinical study designed to address questions posed by the FDA. "We believe that the data from the ongoing pre-clinical study will satisfactorily resolve the FDA's questions," said John O'Donnell, Ph.D, Chief Scientific Officer for Mylan Laboratories. "We will be responding to the FDA in an expeditious manner to move forward with the hypertension approval process."

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 50 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 www.mylan.com.

This press release includes statements that constitute "forward-looking statements," including with regard to nebivolol and the FDA approval process. 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: unexpected regulatory or other delays; the risk that the product will not receive final FDA approval or that it may not ultimately prove to be successful as a therapy for the treatment of hypertension; 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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