Mylan Reports Positive Study on Nebivolol Demonstrating Nebivolol Reduces the Risk of All Cause Mortality and Cardiovascular Hospitalization in Elderly Heart Failure Patients as Reported at the ESC

PITTSBURGH, Aug. 30 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that the SENIORS trial (Study of the Effects of Nebivolol Intervention on Outcomes and Rehospitalization in Seniors with heart failure), conducted in Europe by Menarini, demonstrated that, compared to placebo, nebivolol significantly reduced the combined primary endpoint of all cause mortality and cardiovascular hospital admissions in elderly patients with chronic heart failure. A total of 2,135 patients with an average age of 76 years were randomized in the trial. The results were announced on August 29, 2004, at the annual congress of the European Society of Cardiology (ESC) held in Munich, Germany.

Mylan Vice Chairman and CEO, Robert J. Coury stated, "We would like to extend our congratulations to Menarini for having completed a successful heart failure study with nebivolol. These preliminary results, which were released yesterday at ESC, provide important additional data and further supports our excitement regarding the potential health benefits nebivolol may hold."

SENIORS was a multicenter, multinational, double-blind, placebo- controlled, parallel group, randomized trial. The primary endpoint combined all cause mortality and cardiovascular hospital admissions. Patients recruited to the trial had to have a clinical history of chronic heart failure with either preserved or reduced left ventricular ejection fraction.

Menarini is an Italian based pharmaceutical company who licensed the rights to nebivolol in Europe, South America, the Middle East, Africa and Asia from Janssen Pharmaceutica.

Mylan Laboratories Inc. has exclusive licensing rights to nebivolol in the United States and Canada and previously announced that on June 29, 2004, the Food and Drug Administration (FDA) accepted for filing its New Drug Application (NDA) for the use of nebivolol in the management of hypertension.

As previously stated, the NDA 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 cardioselective blocker that also increases nitric oxide levels. In clinical trials nebivolol was well tolerated with an incidence of adverse events similar to that of placebo.

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 clinical value 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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