New Data on Mylan Bertek's Investigational Beta-Blocker Compound, Nebivolol, Presented at the American Society of Hypertension Meeting

PITTSBURGH, May 18 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc., (NYSE: MYL) announced today that the results of new data on nebivolol, an investigational compound currently under review by the Food and Drug Administration for the treatment of hypertension, were presented at the 20th Annual Scientific Meeting of The American Society of Hypertension (ASH) held in San Francisco. Four separate posters were presented including Phase III clinical results of nebivolol in the treatment of hypertension and the results of pre-clinical studies on the compound's antioxidant properties, its ability to stimulate nitric oxide (NO) release from endothelial cells in White and African American donors, and its high degree of beta-1 adrenergic receptor selectivity, as demonstrated in laboratory studies.

The first abstract, Nebivolol in the Treatment of Patients with Stage 1 and Stage 2 Hypertension: Results of a Randomized, Double-Blind, Placebo- Controlled Study [Abstract #633], was presented by Dr. Robert Weiss, M.D., Director of Research, Cardiovascular Consultants of Maine, Auburn, Maine. The trial was a double-blind, multicenter, randomized, placebo-controlled, parallel-group, dose-ranging study of nebivolol in patients with mild-to- moderate hypertension. Eligible patients (n=909) were randomized to treatment with nebivolol (1.25, 2.5, 5, 10, 20, or 40 mg) or placebo once daily for 12 weeks. The primary efficacy variable was the change from baseline to the end of double-blind treatment (Day 84) in average trough sitting diastolic blood pressure (DBP) for all groups up to and including 20 mg. Safety was assessed by monitoring adverse events (AEs), vital signs (including heart rate), physical examination, electrocardiograms, and laboratory evaluations.

Statistically significant reductions in trough sitting DBP and trough sitting systolic blood pressure (SBP) occurred in the primary and secondary analyses at all doses studied (1.25 mg to 40 mg). Placebo-subtracted reductions in trough sitting blood pressure (SBP/DBP) ranged from 6.6/5.1 mm Hg to 11.7/8.3 mm Hg, in a dose dependent manner. The incidence of adverse events with nebivolol was slightly higher than in placebo treated patients (46.1% vs. 40.7%, respectively.) The most frequently reported treatment- emergent adverse events across all nebivolol doses combined (1.25 mg to 40 mg) were: headache (7.1% vs. 7.4% placebo), fatigue (3.6% vs. 2.5% placebo), nasopharyngitis (2.9% vs. 7.4% placebo) diarrhea (2.8% vs. 2.5% placebo) and dizziness (2.8% vs. 3.7% placebo.) In general, beta blocker related adverse events were low including erectile dysfunction (0.2% vs. 0.0% placebo), depression (0.2% vs. 0.0% placebo), decreased libido (0.1% vs. 0.0% placebo), dyspnea (1.0% vs 0.0% placebo), and bradycardia (0.7% vs. 0.0% placebo). There were significant reductions in heart rate which were dose related. There were few changes in laboratory parameters and mean laboratory values generally remained within normal limits.

A second abstract, Characterization of Beta-1-adrenergic Receptor Selectivity of Nebivolol and Various Other Beta-Blockers in Human Myocardium [Abstract # 322], was presented by Michael R. Bristow, M.D., Ph.D. of University of Colorado Health Sciences Center. In this study cardioselectivity ratios were measured in radioligand assays for nebivolol and seven other beta blocking agents. Binding to beta-1 and beta-2 adrenergic receptors was investigated using 50 pM final concentration of the non-selective beta receptor radioligand [125 I]iodocynanopindolol in the presence or absence of varying cold beta receptor ligand concentrations in membranes prepared from explanted human left ventricular myocardium. The beta-1/beta-2 ratio for each beta blocker investigated was: 321 for nebivolol; 103 for bisoprolol; 93 for betaxolol; 69 for celiprolol; 74 for metoprolol; and 1.0 for the non-selective beta blockers bucindolol, propanolol and carvedilol.

Two additional in vitro studies were presented by Preston Mason, Ph.D. of Brigham and Women's Hospital, Harvard Medical School, entitled: Nebivolol Improves eNOS Function and Nitric Oxide Bioavailability in Endothelial Cells from African Americans [Abstract # 389]; and Membrane Location of Nebivolol Contributes to Antioxidant Activity and Endothelial Nitric Oxide Release in Stroke-Prone Hypertensive Rats [Abstract # 388].

About Mylan

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This press release contains statements that may constitute "forward- looking statements," including with regard to the safety, effectiveness and prospects of nebivolol, a product which has not yet been approved by the FDA. 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 FDA approval or that it may not ultimately prove to be successful as an important 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.

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