FDA Issues Approvable Letter for Nebivolol for the Treatment of Hypertension

NEW YORK and PITTSBURGH, Dec 02, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Forest Laboratories, Inc. (NYSE: FRX) and Mylan Inc. (NYSE: MYL) announced that Mylan has received an approvable letter from the U.S. Food and Drug Administration (FDA) in response to its New Drug Application (NDA) for nebivolol (proposed brand name Bystolic™), a novel beta blocker under review for the treatment of hypertension.

In the approvable letter the FDA indicated that a recent inspection of a backup manufacturing facility in Belgium uncovered deficiencies and that final marketing approval for nebivolol would be contingent upon satisfactory resolution of these deficiencies. The approvable letter did not raise any questions related to safety or efficacy of nebivolol. At this time, the companies and the FDA have agreed upon product labeling text.

The companies anticipate an expeditious resolution to this issue, and Forest continues to plan for a January 2008 launch meeting for Bystolic.

Robert J. Coury, Vice Chairman and CEO for Mylan, stated, "Bystolic (nebivolol) is a valuable asset to our organization and will be to the medical community and the patient population it will serve."

Howard Solomon, Chairman and Chief Executive Officer of Forest, stated: "We remain very encouraged by the prospects for nebivolol and anticipate that, following FDA marketing approval, nebivolol will be an important and welcome new option for physicians. We will work expeditiously with the FDA to secure final marketing approval."

Mylan licensed the U.S. and Canadian rights to nebivolol from Janssen Pharmaceutica N.V. (currently Johnson & Johnson Pharmaceutical Research and Development) in 2001. Nebivolol is already registered and successfully marketed in more than 50 other countries outside of North America for the treatment of hypertension.

Forest licensed nebivolol from Mylan in January 2006 and has responsibility for all sales and marketing as well as current and future development programs. Mylan has retained an option to co-promote the product in the future.

About Forest Laboratories and Its Products

Forest Laboratories (www.frx.com) is a US-based pharmaceutical company dedicated to identifying, developing and delivering products that make a positive difference in peoples' lives. Forest Laboratories' growing product line includes Lexapro® (escitalopram oxalate), an SSRI indicated for adults for the initial and maintenance treatment of major depressive disorder and generalized anxiety disorder; Namenda® (memantine HCl), an N-methyl D-aspartate (NMDA)-receptor antagonist indicated for the treatment of moderate to severe Alzheimer's disease; and Campral®* (acamprosate calcium), indicated in combination with psychosocial support for the maintenance of abstinence from alcohol in patients with alcohol dependence who are abstinent at treatment initiation. In addition to our growing product line, Forest also co-promotes the Daiichi Sankyo, Inc. products Benicar®* (olmesartan medoxomil), an angiotensin receptor blocker, Benicar HCT®* (olmesartan medoxomil-hydrochlorothiazide), an angiotensin receptor blocker and diuretic combination product, and AZOR™* (amlodipine and olmesartan medoxomil) a calcium channel blocker and angiotensin receptor blocker combination product, all indicated for the treatment of hypertension.

*Azor is a trademark of Daiichi Sankyo, Inc.; Benicar and Benicar HCT are registered trademarks of Daiichi Sankyo, Inc.; and Campral is a registered trademark of Merck Sante s.a.s., subsidiary of Merck KGaA, Darmstadt, Germany.

About Mylan

Mylan Inc. is one of the world's leading quality generic and specialty pharmaceutical companies. The Company offers one of the industry's broadest and highest quality product portfolios, a robust product pipeline and a global commercial footprint through operations in more than 90 countries. Through its controlling interest in Matrix Laboratories Limited, Mylan has direct access to one of the largest active pharmaceutical ingredient (API) manufacturers in the world. Dey, L.P., Mylan's fully integrated specialty business, provides the Company with innovative and diversified opportunities in the respiratory and allergy therapeutic areas. For more information about Mylan, please visit www.mylan.com

Except for the historical information contained herein, this release contains forward-looking statements within the meaning of the Private Securities Litigation Reform act of 1995. These statements involve a number of risks and uncertainties, including the difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of

competitive products and pricing, the timely development and launch of new products, and the risk factors listed from time to time in either Forest Laboratories' or Mylan's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and any subsequent SEC filings.

SOURCE Mylan Inc.; Forest Laboratories, Inc.

http://www.mylan.com