# Mylan Confirms Potential First-to-File ANDA on Pfizer's Multi-Billion Dollar Drug Norvasc

PITTSBURGH, Oct 16, 2002 (BUSINESS WIRE) -- Robert J. Coury, Vice Chairman and CEO of Mylan Laboratories Inc. (NYSE: MYL) today acknowledged that Mylan has filed an Abbreviated New Drug Application (ANDA) seeking U.S. Food and Drug Administration (FDA) approval to sell amlodipine besylate tablets (Norvasc®) prior to the expiration of patents owned by Pfizer Inc.

Pfizer filed suit against Mylan, but not before the expiration of the 45 day statutory period, meaning the FDA can approve Mylan's ANDA as soon as the Agency determines that all regulatory requirements have been satisfied.

Mr. Coury believes that Mylan is the first-to-file an amlodipine ANDA containing a "paragraph IV" certification. However, FDA policy prohibits the Agency from confirming first-to-file status until an application receives final approval.

Mr. Coury took exception to comments made by Pfizer regarding the merits of Mylan's amlodipine patent challenge. "Contrary to Pfizer's comments, Mylan has been very selective in choosing which patents to challenge in these cases." He further stated that "it has been eighteen years since the Hatch Waxman amendments became law and during this period Mylan has been very successful in challenging patents and bringing high quality generic products to market sooner than would have otherwise been possible. You don't enjoy that kind of success unless your legal positions are consistently meritorious. Consumers have enjoyed tens of billions of dollars in savings as a result of the success of Mylan and other generic companies and they will continue to reap these savings as we go forward."

"Mylan, which has its own line of branded products and an expanding patent portfolio respects the valid intellectual property rights of others and appreciates the importance of rewarding and protecting truly novel discoveries which advance medical science" stated Coury. He concluded his remarks by stating, "Mylan looks forward to the opportunity to present in court the merits of the Company's defenses to Pfizer's allegations of infringements and that a positive outcome for Mylan in this litigation would obviously represent a tremendous opportunity for the Company and its shareholders."

Mylan Laboratories Inc. is a leading pharmaceutical company that develops, manufactures and markets generic and proprietary products. The Company markets an extensive line of generic products through three business units, Mylan Pharmaceuticals Inc., Mylan Technologies Inc., and UDL Laboratories, Inc. and branded products through its Bertek Pharmaceuticals Inc. subsidiary. For more information, visit www.mylan.com.

To the extent any statements made in this release contain information that is not historical, these statements are essentially forward-looking statements regarding our anticipated financial results and estimates, business prospects and products in research and under going development, all of which involve substantial risks and uncertainties. Such risks and uncertainties are not predictable or quantifiable; consequently, should known or unknown risks or uncertainties materialize, or should our assumptions or estimates prove inaccurate, actual results could differ materially from those expressed or implied by such forward-looking statement. For further details and a discussion of such risks and uncertainties, we encourage you to read Forward-looking Statements found in our Annual Report on Form 10-K for the fiscal year ended March 31, 2002, and in our periodic reports on Forms 10-Q and 8-K (if any).

We assume no obligation to update any forward-looking statements presented here today, whether as a result of new information, future events or otherwise.

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