Mylan No Longer Anticipates Additional Generic Transdermal Fentanyl Approvals During Fiscal 2007

- Company Updates Expectations for Fentanyl Transdermal System -

PITTSBURGH, Aug. 7 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that it no longer anticipates additional generic transdermal fentanyl approvals during fiscal 2007, which ends on March 31, 2007. Mylan's Fentanyl Transdermal System is the only FDA approved, AB-rated generic alternative to Ortho-McNeil's Duragesic® patch. An FDA filing from PriCara (a unit of Ortho-McNeil) recently became available for public viewing on the FDA website.

The filing supports Mylan's position and its request in an earlier citizen petition for the FDA to require all applicants for fentanyl transdermal systems to conduct their own individual studies to determine the effect of an overlay with their respective patches. Based on the information in the PriCara filing as well as the safety issues raised in the three fentanyl citizen petitions currently filed with the FDA, Mylan no longer anticipates that additional generic fentanyl products will be approved during its current fiscal year.

Robert J. Coury, Mylan's Vice Chairman and Chief Executive Officer commented, "We've been very clear with the financial community concerning our expectations for this important product, and up until this point, we felt it was appropriate to anticipate additional generic fentanyl approvals in our projections for fiscal 2007. After having reviewed this most recent filing, it is now clear that both Mylan and Ortho-McNeil agree that there are significant issues for the FDA to consider. Mylan will never speak for the FDA, but the agency has clearly demonstrated that they will judiciously and responsibly evaluate all issues surrounding this highly advanced transdermal product to protect the safety of patients. We fully support the agency in its efforts. Given the FDA consideration of citizen petitions is typically an extended period of time -- six to ten months or longer -- and given that both Mylan and Ortho-McNeil have now independently raised the same need for a clinical overlay study, we anticipate that the FDA will remain consistent in their approach and in requirements for approval. Both Mylan and Ortho-McNeil have completed the clinical overlay studies. We believe at a minimum additional applicants will be required to complete similar studies to demonstrate the safety of their products."

At this time, Mylan is not revising the fiscal 2007 adjusted EPS guidance of $1.35 - $1.55 that the company provided on July 26, as the range of guidance already allows for the potential of increased earnings based on a lack of additional generic transdermal fentanyl approvals.

Mr. Coury further commented: "As we've stated many times in the past we continually monitor developments with all of our products and when additional information becomes available that changes our expectations we will revise our guidance accordingly."

About Mylan Laboratories

Mylan Laboratories Inc. is a leading pharmaceutical company with three principal subsidiaries, Mylan Pharmaceuticals Inc., Mylan Technologies Inc. and UDL Laboratories, 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 the entry of additional competition for the Company's fentanyl transdermal system and timing of such entry; the FDA's consideration of citizen petitions and the anticipated duration of its approval process; the requirements the FDA may impose on additional applicants; and the Company's earnings expectations. 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: a regulatory or other decision outside of the Company's control impacting the entry of fentanyl competition; risks inherent in administrative proceedings; an unexpected change in the anticipated timing of a decision by the FDA; prevailing market conditions; changes in economic and financial conditions of the Company's business; and uncertainties and matters beyond the control of management, which could affect the Company's earnings guidance, as well as the subjectivity inherent in any probability weighted analysis underlying the Company's assumptions and estimates with respect to the future; 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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