Mylan Announces Final Approval for Additional Strengths of Estradiol Transdermal Systems

PITTSBURGH, July 25 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that the U.S. Food and Drug Administration has granted final approval for Mylan Technologies Inc.'s (MTI) supplemental Abbreviated New Drug Application for Estradiol Transdermal Systems, 0.0375 mg/day and 0.06 mg/day. These products will be added to the four additional strengths of Estradiol Transdermal Systems that Mylan is already marketing.

Estradiol Transdermal Systems are indicated for the treatment of moderate to severe vasomotor symptoms associated with menopause. They are the AB-rated generic equivalent of Berlex's Climara Transdermal Systems®.

Mylan is the first company to file a supplemental ANDA for Estradiol Transdermal Systems, 0.0375 mg/day and 0.06 mg/day, and has been awarded a 180-day period of marketing exclusivity for these two strengths.

Mylan expects to launch this product shortly.

Mylan Laboratories Inc. is a leading pharmaceutical company with three principal subsidiaries: Mylan Pharmaceuticals Inc., Mylan Technologies Inc. and UDL Laboratories Inc. Mylan develops, licenses, manufactures, markets and distributes an extensive line of generic and proprietary products.

For more information about Mylan, please visit www.mylan.com.

This press release includes statements that constitute "forward-looking statements," including with regard to the launch of Estradiol Transdermal Systems, 0.0375 mg/day and 0.06 mg/day. 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: the possible negative effects of any interruption of manufacture of the product; uncertainties regarding market acceptance and demand for the product; dependence on third- party suppliers and distributors for raw materials; 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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