Mylan Receives Tentative Approval for Oxybutynin Chloride Extended-release Tablets

PITTSBURGH, Jan 18, 2005 /PRNewswire-FirstCall via COMTEX/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that the U.S. Food and Drug Administration (FDA) has granted tentative approval for Mylan Pharmaceuticals Inc.'s Abbreviated New Drug Applications (ANDAs) for Oxybutynin Chloride Extended-release Tablets, 5 mg and 10 mg. Oxybutynin Chloride ER Tablets are the generic version of Alza Corporation's Ditropan XL® Extended-release Tablets.

Mylan believes it is the first generic drug company to file ANDAs with the FDA for 5 mg and 10 mg Ditropan XL®, and as such, the company may be eligible for 180 days of market exclusivity.

Mylan Laboratories Inc. is a leading pharmaceutical company with four subsidiaries, Mylan Pharmaceuticals Inc., Mylan Technologies Inc., UDL Laboratories Inc. and Mylan Bertek Pharmaceuticals Inc., that develop, license, manufacture, market and distribute an extensive line of generic and proprietary products.

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

This press release includes statements that constitute "forward-looking statements," including with regard to the Company's beliefs as to filing status and market exclusivity and the receipt of final FDA approval. 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 difficulty of predicting FDA and other regulatory authority approvals; the impact of any competition from so-called "authorized generics"; acceptance and demand for pharmaceutical products; the impact of competitive products and pricing; dependence on third-party distributors and suppliers for raw materials; the impact of industry regulation and changes that may affect exclusivity; 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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