



## **Mylan Laboratories Inc. Announces First ANDA Approval for Isotretinoin; Bertek Pharmaceuticals Inc. to Market Amnesteem**

PITTSBURGH--(BUSINESS WIRE)--Nov. 11, 2002--Mylan Laboratories Inc. (NYSE: MYL) today announced that the Food and Drug Administration has granted the first Abbreviated New Drug Application (ANDA) approval for isotretinoin soft-gelatin capsules.

Mylan's branded subsidiary Bertek Pharmaceuticals Inc. will market isotretinoin under the trade name Amnesteem™ in 10 mg, 20 mg and 40 mg strengths.

Mylan acquired the exclusive U.S. marketing rights for isotretinoin through a three-way supply and distribution agreement with Genpharm Inc., Toronto, Canada, which submitted the ANDA, and the Oral Technologies business of Cardinal Health, Inc. (NYSE:CAH), which will manufacture and package the product.

Amnesteem is bioequivalent and thus therapeutically equivalent to Roche Laboratories' Accutane® capsules. Accutane, which is prescribed for the treatment of severe recalcitrant nodular acne, currently has annual sales in excess of one-half billion dollars in the U.S.

Bertek will market Amnesteem through its detail sales force and will provide a comprehensive education/risk management program to patients, pharmacists and doctors, with a focus on dermatologists.

Bertek will offer Amnesteem in both 30 capsule and 100 capsule packages containing either three or ten blister packs of 10 capsules each.

Bertek Pharmaceuticals Inc., based in Research Triangle Park, NC, develops and licenses proprietary pharmaceuticals, with a current focus on dermatology, neurology and cardiology. For more information, visit [www.bertek.com](http://www.bertek.com).

Mylan Laboratories Inc. is a leading pharmaceutical company that develops, manufactures and markets generic and proprietary prescription products. Mylan has two operating segments that market an extensive line of generic and branded products through four business units: Mylan Pharmaceuticals Inc., Mylan Technologies Inc., UDL Laboratories, Inc. and Bertek Pharmaceuticals Inc. For more information about Mylan, visit [www.mylan.com](http://www.mylan.com).

This press release may contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. We refer you to the risk factors and other disclosures contained in our most recent Form 10-K and other periodic SEC filings.

We undertake no duty to update our forward-looking statements, even though our situation may change in the future.

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