



Mylan Receives Tentative FDA Approval for First-to-File Generic Version of Blood Pressure Drug Benicar HCT(R)

- Mylan also announces tentative approval for generic version of Uroxatral® ER -

PITTSBURGH, Oct. 22 /PRNewswire-FirstCall/ -- Mylan Inc. (NYSE: MYL) today announced that its subsidiary, Mylan Pharmaceuticals Inc., received tentative approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Olmesartan Medoxomil and Hydrochlorothiazide Tablets, 20 mg/12.5 mg, 40 mg/12.5 mg and 40 mg/25 mg.

Olmesartan Medoxomil Hydrochlorothiazide Tablets, indicated for the treatment of high blood pressure, are the generic version of Daiichi Sankyo's Benicar HCT®. This product had annual U.S. sales of approximately \$535 million for the 12 months ending June 30, 2008, for the noted strengths, according to IMS Health.

Mylan Pharmaceuticals submitted its original application for this product to the FDA on Feb. 14, 2007, and believes it is the first company to submit a substantially complete ANDA containing a Paragraph IV certification. Under the provisions of the Hatch-Waxman Act, it is anticipated that Mylan Pharmaceuticals will be entitled to 180 days of marketing exclusivity for Olmesartan Medoxomil Hydrochlorothiazide upon FDA approval.

In addition, Mylan Pharmaceuticals recently received tentative FDA approval for its ANDA for Alfuzosin Hydrochloride (HCl) Extended-release (ER) Tablets, 10 mg. Alfuzosin HCl ER Tablets, indicated for the treatment of an enlarged prostate or Benign Prostatic Hyperplasia (BPH), are the generic version of Sanofi Aventis' Uroxatral® ER. This product had annual U.S. sales of approximately \$168 million for the 12 months ending June 30, 2008, for the noted strength, according to IMS Health.

Currently, Mylan has 108 ANDAs pending FDA approval, 22 of which are potential first-to-file opportunities.

Mylan Inc., which provides products to customers in more than 140 countries and territories, ranks among the leading diversified generic and specialty pharmaceutical companies in the world. The company maintains one of the industry's broadest -- and highest quality -- product portfolios, supported by a robust product pipeline; owns a controlling interest in the world's second largest active pharmaceutical ingredient manufacturer; and operates a specialty business focused on respiratory and allergy therapies. For more information, please visit <http://www.mylan.com>.

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