Mylan Receives FDA Approval for Generic Version of Prostate Cancer Treatment Casodex (R)

Begins shipment of product

PITTSBURGH, July 7 /PRNewswire-FirstCall/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Pharmaceuticals Inc. has received approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Bicalutamide Tablets, 50 mg.

Bicalutamide Tablets are the generic version of AstraZeneca's prostate cancer treatment Casodex®, which had total U.S. sales of approximately $322 million for the 12 months ending March 31 for the same strength, according to IMS Health. Mylan has begun to ship this product.

Currently, Mylan has 118 ANDAs pending FDA approval representing $82.8 billion in annual brand sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing $16.7 billion in annual brand sales, according to IMS Health.

Mylan Inc., which provides products to customers in more than 140 countries and territories, ranks among the leading diversified generics 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 third largest active pharmaceutical ingredient manufacturer; and operates a specialty business focused on respiratory and allergy therapies. For more information, please visit www.mylan.com.

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