Mylan Receives FDA Approval for Additional Strengths of the Antipsychotic Haloperidol

Begins shipment of products

PITTSBURGH, July 20 /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 supplemental Abbreviated New Drug Application (ANDA) for Haloperidol Tablets USP, 10 mg and 20 mg. These strengths are in addition to Mylan's currently marketed 0.5 mg, 1 mg, 2 mg and 5 mg strengths of the product.

Haloperidol Tablets are an antipsychotic typically used to reduce the symptoms of schizophrenia and uncontrollable tics and outbursts associated with Tourette syndrome. Haloperidol had total U.S. sales of approximately $21 million for the 12 months ending March 31 for the same strengths, according to IMS Health. Mylan has begun to ship this product.

Currently, Mylan has 119 ANDAs pending FDA approval representing $84.7 billion in annual brand sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, representing $16.6 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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