Mylan Receives FDA Approval for Additional Strength of Generic Restoril(R)

Product shipment has begun

PITTSBURGH, June 17 /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 Temazepam Capsules USP, 22.5 mg. This strength is in addition to Mylan's currently marketed 15 mg and 30 mg strengths of the product.

Temazepam Capsules are the generic version of Mallinckrodt's Restoril®, a sleep aid, which had total U.S. sales of approximately $6 million for the 12 months ending March 31, according to IMS Health. Mylan has begun shipping this product.

Currently, Mylan has 118 ANDAs pending FDA approval representing $82.7 billion in annual brand sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, which represent $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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