Mylan Receives Approval for Generic Version of ValtrexÃ,®

Bio-Medicine.Org

PITTSBURGH, May 26 /PRNewswire-FirstCall/ -- Mylan Inc. (Nasdaq: MYL [1]) today announced that its subsidiary Matrix Laboratories Limited has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Valacyclovir Hydrochloride Tablets, 500 mg (base) and 1000 mg (base), the generic version of GlaxoSmithKline's Valtrex®, a treatment for the herpes virus infection. The product is being distributed by Mylan Pharmaceuticals Inc. and is shipping to customers.

Valacyclovir Hydrochloride Tablets had U.S. sales of approximately $2.15 billion for the 12 months ending March 31, 2010, according to IMS Health.

Currently, Mylan has 142 ANDAs pending FDA approval representing $95.6 billion in annual brand sales, according to IMS Health. Thirty-seven of these pending ANDAs are potential first-to-file opportunities, representing $19.6 billion in annual brand sales, for the 12 months ending Dec. 31, 2009, according to IMS Health.

Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 140 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios supported by a robust product pipeline; operates one of the world's largest active pharmaceutical ingredient manufacturers; and runs a specialty business focused on respiratory, allergy and psychiatric therapies. For more information, please visit

SOURCE [2]

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