Mylan Receives Approval for Nabumetone Tablets

Bio-Medicine.Org

PITTSBURGH, July 14 /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 Nabumetone Tablets USP, 500 mg and 750 mg. The product was determined to be bioequivalent and, therefore, therapeutically equivalent to Nabumetone Tablets, a treatment for osteoarthritis and rheumatoid arthritis. The product will be distributed by Mylan Pharmaceuticals Inc.

Nabumetone Tablets had U.S. sales of approximately $68 million for the 12 months ending March 31, 2010, according to IMS Health.

Currently, Mylan has 134 ANDAs pending FDA approval representing $93.8 billion in annual brand sales, according to IMS Health. Thirty-nine of these pending ANDAs are potential first-to-file opportunities, representing $20.2 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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