Mylan Receives Approval for Generic Version of Prograf(R) Capsules

PITTSBURGH, Sept 21, 2010 /PRNewswire via COMTEX News Network/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Pharmaceuticals Inc. has received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Tacrolimus Capsules, 0.5 mg, 1 mg and 5 mg, the generic version of Astellas' Prograf(R) Capsules, a treatment to prevent rejection in people who have received certain organ transplants.

Tacrolimus Capsules had U.S. sales of approximately $944 million for the 12 months ending June 30, 2010, according to IMS Health. The product will launch immediately.

Currently, Mylan has 137 ANDAs pending FDA approval representing $92 billion in annual brand sales, according to IMS Health. Forty-two of these pending ANDAs are potential first-to-file opportunities, representing $21 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 www.mylan.com.

SOURCE Mylan Inc.