Mylan Receives Tentative FDA Approval for Generic Version of Lipitor®

PITTSBURGH, Feb. 2, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Mylan Laboratories Limited (formerly Matrix Laboratories Limited) has received tentative approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Atorvastatin Calcium Tablets, 10 mg (base), 20 mg (base), 40 mg (base) and 80 mg (base). Atorvastatin Calcium is the generic equivalent to Pfizer's Lipitor® Tablets, indicated for the prevention of cardiovascular disease and hypercholesterolemia.

Lipitor had U.S. sales of $8.2 billion for the twelve months ending Dec. 31, 2011, according to IMS Health.

Currently, Mylan has 173 ANDAs pending FDA approval representing $98.5 billion in annual sales, according to IMS Health. Forty-two of these pending ANDAs are potential first-to-file opportunities, representing $26.8 billion in annual brand sales, for the 12 months ending June 30, 2011, 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 150 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 about Mylan, please visit www.mylan.com. For more information about generic drugs, please visit www.ChoosingGenerics.com.

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