Mylan Launches First Generic Version of Lescol® Capsules

PITTSBURGH, April 13, 2012 /PRNewswire/ -- 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 Fluvastatin Capsules USP, 20 mg and 40 mg, the first generic version of Novartis' Lescol® Capsules. This product is indicated for the treatment of both familial and nonfamilial hypercholesterolemia and mixed dyslipidemia. It is also indicated for the secondary prevention of cardiovascular disease.[1]

Pursuant to a settlement and license agreement with Novartis, Mylan was granted a license permitting launch prior to the expiration of the pediatric exclusivity associated with U.S. Patent No. 5,356,896, which expires on June 12, 2012.

Lescol Capsules had U.S. sales of approximately $27.9 million for the 12 months ending Dec. 31, 2011, according to IMS Health. Mylan has begun shipping its generic version of this product.

Currently, Mylan has 172 ANDAs pending FDA approval representing $100.2 billion in annual sales, according to IMS Health. Forty of these pending ANDAs are potential first-to-file opportunities, representing $25.7 billion in annual brand sales, for the 12 months ending Dec. 31, 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 allergy, respiratory and psychiatric therapies. For more information about Mylan, please visit www.mylan.com. For more information about generic drugs, please visit www.ChoosingGenerics.com.

[1] Fluvastatin should not be used in patients with hypersensitivity to any component of this medication, patients with liver disease, women who are pregnant or may become pregnant or mothers who are breast feeding.

SOURCE Mylan Inc.