Mylan Receives Approval for First-to-File Generic Sular® Extended-Release Tablets

Company will have 180 days of marketing exclusivity on all strengths

PITTSBURGH, Jan. 28, 2011 /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 Nisoldipine Extended-release (ER) Tablets, 8.5 mg, 17 mg, 25.5 mg and 34 mg. Mylan was the first company to have filed a substantially complete ANDA containing a Paragraph IV certification for Nisoldipine ER Tablets and has been awarded 180 days of marketing exclusivity.

Nisoldipine ER Tablets are the generic version of Shionogi Pharma's Sular® Tablets, a treatment for hypertension. Nisoldipine ER Tablets had U.S. sales of approximately $103 million for the 12 months ending Sept. 30, 2010, according to IMS Health. Product from Mylan is available for shipment.

Currently, Mylan has 168 ANDAs pending FDA approval representing $97.7 billion in annual sales, according to IMS Health. Forty-five of these pending ANDAs are potential first-to-file opportunities, representing $24.2 billion in annual brand sales, for the 12 months ending June 30, 2010, 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 about Mylan, please visit www.mylan.com. For more information about generic drugs, please visit www.ChoosingGenerics.com.

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