Mylan Receives Final FDA Approval for the Generic Version of the Antidepressant Sarafem (R) Pulvules(R) Capsules

PITTSBURGH, Nov. 18 /PRNewswire-FirstCall/ -- Mylan Inc. (NYSE: MYL) today announced that its subsidiary, Mylan Pharmaceuticals Inc., received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Fluoxetine Capsules USP, 10 mg and 20 mg.

Fluoxetine Capsules, indicated for the treatment of premenstrual dysphoric disorder (PMDD) are the generic version of Eli Lilly's Sarafem® Pulvules® Capsules. This product had annual U.S. sales of approximately $19.2 million for the 12 months ending Sept. 30, 2008, for the noted strengths, according to IMS Health. Shipment of the product will begin immediately.

Currently, Mylan has 112 ANDAs pending FDA approval, 23 of which are potential first-to-file opportunities.

Mylan Inc., which provides products to customers in more than 140 countries and territories, ranks among the leading diversified generic and specialty pharmaceutical companies in the world. The company maintains one of the industry's broadest - and highest quality - product portfolios, supported by a robust product pipeline; owns a controlling interest in the world's third largest active pharmaceutical ingredient manufacturer; and operates a specialty business focused on respiratory and allergy therapies. For more information, please visit www.mylan.com.

SOURCE Mylan Inc. 11/18/2008 /CONTACT: Media, Michael Laffin, +1-724-514-1968, Investors, Dan Crookshank, +1-724-514-1813, both of Mylan Inc. (MYL)