Mylan Receives FDA Approval for First-to-File Generic Depakote(R) ER

Company will have 180 days of marketing exclusivity on the 500 mg strength

PITTSBURGH, Jan. 30 /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 Divalproex Sodium Extended-release (Divalproex ER) Tablets, 250 mg and 500 mg.

Mylan has been awarded 180 days of marketing exclusivity for the 500 mg strength, which it will begin to ship Feb. 2. Mylan was the first company to file a substantially complete ANDA containing a Paragraph IV certification for the 500 mg strength. Mylan is shipping the 250 mg strength immediately.

Divalproex ER Tablets are the generic version of Abbott Laboratories' Depakote® ER and had U.S. sales of approximately $901 million for the 12 months ending Sept. 30, 2008, with $789 million for the 500 mg strength and $112 million for the 250 mg strength.

Currently, Mylan has 119 ANDAs pending FDA approval, 33 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.

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