



Mylan's Alphapharm Victorious in Patent Challenge on First-to-File Opportunity Razadyne (R) Tablets

Receives FDA Approval for Generic Version

PITTSBURGH, Aug. 29 /PRNewswire-FirstCall/ -- Mylan Inc. (NYSE: MYL) today announced that its subsidiary Alphapharm Pty Limited won a favorable decision in patent litigation against it and Barr Laboratories Inc. relating to Galantamine Tablets, USP, the generic version of Ortho-McNeil's Razadyne[®] Tablets, 4 mg, 8 mg and 12 mg.

On August 27, the U.S. District Court for the District of Delaware invalidated the sole "Orange Book" patent (U.S. Patent No. 4,663,318) asserted against Alphapharm by Janssen Pharmaceutica NV, Janssen LP and Synaptech Inc. Alphapharm was first to file an Abbreviated New Drug Application (ANDA), along with other generics companies, for Galantamine Tablets.

"We are very pleased with the court's ruling on this first-to-file patent challenge, which once again continues to underscore our ability to effectively pursue and monetize Paragraph IV opportunities," said Mylan Vice Chairman and CEO Robert J. Coury. "This is yet another example of our continued and successful commitment to provide affordable medications to the patients who need them the most."

The U.S. Food and Drug Administration (FDA) yesterday approved Alphapharm's ANDA. Mylan Pharmaceuticals, another Mylan subsidiary, intends to immediately launch the product on behalf of Alphapharm. Alphapharm and other applicable ANDA holders will be awarded 180 days of shared marketing exclusivity.

Razadyne Tablets, indicated for the treatment of mild to moderate dementia associated with Alzheimer's disease, had annual U.S. sales of approximately \$102 million for the 12 months ending June 30, 2008, for the same strengths. Currently, Mylan has 93 ANDAs pending FDA approval, 22 of which are potential first-to-file opportunities.

Mylan Inc., with a presence in more than 90 countries, 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 second largest active pharmaceutical ingredient manufacturer; and operates a specialty business focused on respiratory and allergy therapies.

SOURCE Mylan Inc.

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