Mylan Sues FDA Seeking Ruling That Teva Holds No Exclusivity for Its Generic Version of Provigil®

Mylan Seeks to Obtain 180-Day Exclusivity

PITTSBURGH, April 5, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary, Mylan Pharmaceuticals Inc., has filed suit against the U.S. Food and Drug Administration (FDA) in the U.S. District Court for the District of Columbia seeking to overturn a decision by FDA, which awarded Teva sole 180-day exclusivity for the generic version of its affiliate Cephalon's Provigil®.

The Complaint alleges that Teva did not maintain valid paragraph IV (PIV) certifications as a result of its acquisition of Cephalon. The Complaint states that, once Teva became the owner of Cephalon, Teva could no longer infringe its own patents through a PIV certification and that Teva therefore is not entitled to exclusivity based on patent certifications. Mylan also alleges that FDA should have found that Mylan is the sole first filer on one of the Orange Book Patents for Provigil, that Teva abandoned its abbreviated new drug application (ANDA), and that FDA should have approved Mylan's ANDA for this product. Mylan is seeking an immediate order from the Court entitling it to exclusivity and immediate approval for its ANDA.

The Complaint also alleges that FDA's decision, which blocks Mylan and other generic entrants from launching their generic Provigil products, is unlawful. Mylan believes the Federal Trade Commission did not contemplate the current outcome when it imposed its conditions on the Teva/Cephalon merger. As a result of FDA's decision, only one party—Teva/Cephalon—is controlling 100% of the supply of product in the marketplace. This is despite the fact that Cephalon previously agreed to a Mylan launch of its generic product no later than April 6, 2012.

Mylan is seeking immediate equitable relief from the Court requiring FDA to approve Mylan's ANDA.

According to IMS Health, Provigil had U.S. sales of approximately $1.1 billion for the 12 months ending Dec. 31, 2011.

This press release includes statement that may constitute "forward-looking statements", including with regard to pending litigation. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, risks inherent in legal and regulatory matters and the other risks detailed in the company's filings with the Securities and Exchange Commission. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.

About Mylan
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 respiratory, allergy and psychiatric therapies. For more information about Mylan, please visit www.mylan.com.

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