Mylan Confirms First-to-File Patent Challenge Relating to AMRIX(R)

- Mylan believes it has 180 days of sole marketing exclusivity -

PITTSBURGH, Dec. 1 /PRNewswire-FirstCall/ -- Mylan Inc. (NYSE: MYL) today confirmed that the company and its subsidiary, Mylan Pharmaceuticals Inc., have been sued by Cephalon Inc., Eurand Inc. and Anesta AG in connection with the filing of an Abbreviated New Drug Application (ANDA) for Cyclobenzaprine Hydrochloride (HCl) Extended-release (ER) Capsules, 15 mg and 30 mg, the generic version of AMRIX® Capsules.

Mylan believes it is the first company to have filed a substantially complete ANDA containing a Paragraph IV certification for the product and expects to be awarded 180 days of sole marketing exclusivity once final approval is obtained. Mylan filed its ANDA with the U.S. Food and Drug Administration (FDA) in August. Cephalon, Eurand and Anesta filed a lawsuit Nov. 26 in the U.S. District Court for the District of Delaware alleging infringement of U.S. Patent No. 7,387,793.

Cyclobenzaprine HCl ER Capsules, a muscle relaxant introduced to the market in October 2007, had approximately $53 million in sales for the twelve months ending Sept. 30 and approximately $19 million for the quarter ending Sept. 30, according to IMS Health.

Currently, Mylan has 113 ANDAs pending FDA approval, 24 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.

This press release includes statements that constitute "forward-looking statements," including with regard to the expected first to file status and 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: the use of legal, regulatory and legislative strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in legal and regulatory processes; 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.

SOURCE Mylan Inc.
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