Mylan Announces Settlement Agreement for its First-to-File Generic Version of Vivelle-Dot®

- Agreement includes a no-later-than Dec. 16, 2013 launch -

PITTSBURGH, Nov. 21, 2011 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today announced that it has settled a patent litigation lawsuit with Novartis Pharmaceuticals Corporation related to Vivelle-Dot® (Estradiol Transdermal System USP, Twice-Weekly, 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day and 0.075 mg/day and 0.1 mg/day).

Pursuant to the agreement, pending litigation will be dismissed, and Mylan will receive a patent license to begin selling generic versions of the product on Dec. 16, 2013, or earlier under certain circumstances. Additional details of the settlement are confidential, and the agreement itself is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

Mylan was the first company to have filed a substantially complete abbreviated new drug application (ANDA) containing a Paragraph IV certification with the U.S. Food and Drug Administration (FDA) for Estradiol Transdermal System USP, Twice-Weekly. This product had total U.S. sales of $240 million for the 12 months ending Sept. 30, 2011, according to IMS Health.

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. For more information about generic drugs, please visit www.ChoosingGenerics.com.

This press release includes statements that constitute "forward-looking statements," including with regard to the settlement and the marketing of the product. 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: any legal or regulatory challenges to the settlement; 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 periodic 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.