

Mylan Receives Final FDA Approval for First Generic Version of Doryx® Tablets, 150 mg

FDA Denies Warner Chilcott's Citizen Petition

PITTSBURGH, Feb. 9, 2012 /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 Doxycycline Hyclate Delayed-release (DR) Tablets USP, 150 mg. This product is the generic version of Mayne Pharma's Doryx® (marketed by Warner Chilcott), which is a tetracycline-class antimicrobial.

Mylan CEO Heather Bresch commented: "We are gratified by FDA's approval of our generic Doryx 150 mg product. We have strongly believed from the very beginning that Warner Chilcott's citizen petition in reference to this product was baseless and are extremely pleased that FDA has now denied this petition."

Mylan has agreed that it will not launch its generic Doryx product until after a decision is issued in Warner Chilcott's patent infringement lawsuit against Mylan. This trial is underway in the U.S. District Court for the District of New Jersey (Newark) and a decision is currently expected in March.

Doxycycline Hyclate DR Tablets had U.S. sales of approximately \$264.1 million for the 12 months ending Dec. 31, 2011, according to IMS Health.

Currently, Mylan has 173 ANDAs pending FDA approval representing \$98.3 billion in annual sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing \$26.6 billion in annual brand sales, for the 12 months ending June 30, 2011, according to IMS Health.

This press release includes statements that constitute "forward-looking statements," including with regard to product approvals and regulatory matters. 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 impact and effects of legal or regulatory proceedings; uncertainties and matters beyond the control of management; 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.

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.mylan.com.

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