Mylan Confirms Four First-to-File Challenges

PITTSBURGH, March 26 /PRNewswire-FirstCall/ -- Mylan Inc. (Nasdaq: MYL) today announced that it and/or a subsidiary have been sued in connection with four separate "first-to-file" Abbreviated New Drug Applications (ANDA) filed with the U.S. Food and Drug Administration (FDA).

Mylan and Alphapharm Pty. Ltd were sued by Sepracor Inc. in the U.S. District Court of New Jersey in connection with the ANDA filing for Eszopiclone Tablets, 1 mg, 2 mg and 3 mg. Eszopiclone Tablets are the generic version of Sepracor's insomnia treatment Lunesta® Tablets, which had approximately $796 million in U.S. sales for the twelve months ending Dec. 31, 2008, according to IMS Health.

Mylan Pharmaceuticals Inc. was sued by OSI Pharmaceuticals Inc., Pfizer Inc. and Genentech Inc. in the U.S. District Court in Delaware in connection with the ANDA filing for Erlotinib Hydrochloride (HCl) Tablets, 25 mg, 100 mg and 150 mg. Erlotinib HCl Tablets are the generic version of OSI Pharmaceuticals' lung cancer treatment Tarceva® Tablets, which had approximately $492 million in U.S. sales for the twelve months ending Dec. 31, 2008, according to IMS Health.

Mylan, Mylan Pharmaceuticals and Matrix Laboratories Limited, in which Mylan owns a majority interest, were sued by Shire Canada Inc., Shire International Licensing B.V. and Shire U.S. Inc. in the U.S. District Court for the Southern District of New York in connection with the ANDA filing for Lanthanum Carbonate Chewable Tablets, 500 mg, 750 mg and 1000 mg. Lanthanum Carbonate Chewable Tablets are the generic version of Shire's kidney disease treatment Fosrenol®, which had approximately $108 million in U.S. sales for the twelve months ending Dec. 31, 2008, according to IMS Health.

Mylan Pharmaceuticals was sued by Galderma Laboratories Inc., Galderma Laboratories LP, The Research Foundation of the State University of New York and New York University in the U.S. District Court of Delaware in connection with the ANDA filing for Doxycycline Delayed-release (DR) Capsules USP, 40 mg. Doxycycline DR Capsules are the generic version of Galderma's adult rosacea treatment Oracea® Capsules, which had approximately $82 million in U.S. sales for the twelve months ending Dec. 31, 2008, according to IMS Health.

Mylan believes it is among the first companies to have filed substantially complete ANDAs containing a Paragraph IV certification for three of these products and expects to be awarded 180 days of shared marketing exclusivity once final approvals are obtained. With Doxycycline DR Capsules, Mylan believes it could have sole marketing exclusivity for the 180 day period. Currently, Mylan has 118 ANDAs pending FDA approval, 33 of which are potential first-to-file opportunities.

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.

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.

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