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Mylan Announces Settlement Agreement for First-to-File Generess® Fe

PITTSBURGH, April 15, 2014 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today confirmed that it and its partner Famy Care Ltd. have entered into a settlement and license agreement with Warner Chilcott Company, LLC, settling the parties' litigation in connection with Mylan's filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Norethindrone and Ethinyl Estradiol Chewable Tablets 0.8 mg/0.025 mg and Ferrous Fumarate Chewable Tablets. This product is the generic version of Generess® Fe Tablets, which are indicated for the prevention of pregnancy (1).

Under the terms of the settlement and license agreement, Mylan may begin to sell a generic version of Generess Fe Tablets on April 1, 2015, or earlier under certain circumstances, and upon receiving final FDA approval. Alternatively, Mylan will be permitted to launch an authorized generic version of Actavis' product beginning on October 1, 2015. Pursuant to the agreement, the parties pending litigation will be dismissed. All other terms and conditions of the settlement and license agreement are confidential, and the agreement itself is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

Mylan believes that its partner, Famy Care Ltd., is the first company to have filed a substantially complete ANDA containing a Paragraph IV certification with the U.S. FDA for Norethindrone and Ethinyl Estradiol Chewable Tablets 0.8 mg/0.025 mg and Ferrous Fumarate Chewable Tablets. For the 12 months ending Dec. 31, 2013, Generess Fe Tablets had U.S. sales of approximately \$81.83 million, according to IMS Health.

Currently, Mylan has 187 ANDAs pending FDA approval representing \$94.9 billion in annual brand sales, according to IMS Health. Forty-two of these pending ANDAs are potential first-to-file opportunities, representing \$25.4 billion in annual brand sales, for the 12 months ending Dec. 31, 2013, according to IMS Health. When including ANDAs associated with Mylan's recent acquisition of Agila, the company now has a total of 304 ANDAs pending FDA approval.

This press release includes statements that constitute "forward-looking statements," including with regard to the settlement of litigation and sales of products. 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 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 is a global pharmaceutical company committed to setting new standards in health care. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 140 countries and territories. Our workforce of more than 20,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. mylan.com

(1) Cigarette smoking increases the risk of serious cardiovascular side effects from oral contraceptive use and this risk increases with age. Women who use oral contraceptives should be advised to not smoke. Consult your physician prior to beginning oral contraceptive use.

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