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Mylan Confirms First-to-File Patent Challenge Relating to Minivelle®

- Expects to be eligible for 180 days of marketing exclusivity -

POTTERS BAR, England and PITTSBURGH, May 5, 2015 /PRNewswire/ -- Mylan N.V. (Nasdaq: MYL) today confirmed that it and its subsidiaries Mylan Pharmaceuticals Inc. and Mylan Technologies Inc. have been sued by Noven Pharmaceuticals Inc. and Hisamitsu Pharmaceutical Co., Inc., in connection with the filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for Estradiol Transdermal System, USP, "Twice-Weekly" 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day and 0.1 mg/day. This product is the generic version of Minivelle®, which is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause and the prevention of postmenopausal osteoporosis.

Mylan CEO Heather Bresch commented: "Our ANDA for a generic Minivelle is one of six Mylan applications for transdermal products pending FDA approval, representing \$3.6 billion in annual sales. Mylan currently markets seven transdermal product families in the U.S., of which three form part of our women's health portfolio, and we look forward to continue expanding access to high quality medicines for patients in this space."

Mylan believes that it is the first company, or among the first companies, to have filed a substantially complete ANDA containing a Paragraph IV certification for this product and expects to be eligible for 180 days of marketing exclusivity upon receiving final FDA approval. The plaintiffs filed suit against the Mylan companies in the United States District Court in the District of Delaware.

For the 12 months ending February 2015, Minivelle had U.S. sales of approximately \$115 million, according to IMS Health.

Currently, Mylan has 273 ANDAs pending FDA approval representing \$106.9 billion in annual sales, according to IMS Health. Forty-seven of these pending ANDAs are potential first-to-file opportunities, representing \$31.1 billion in annual brand sales, for the 12 months ending December 31, 2014, according to IMS Health.

This press release includes statements that constitute "forward-looking statements," including with regard to product approvals, the expected first-to-file status, pending litigation, and marketing 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: the impacts of competition; changes in economic and financial conditions of the company's business; strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in legal and regulatory processes; uncertainties and other 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 is a global pharmaceutical company committed to setting new standards in healthcare. 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 around 1,400 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 about 145 countries and territories. Our workforce of approximately 30,000 people is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

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