September 2, 2015

Mylan Confirms the U.S. Patent and Trademark Office Institutes Inter Partes Review Proceeding against Third Copaxone® 40 mg/mL Dosing Patent on All Claims

HERTFORDSHIRE, England and PITTSBURGH, Sept. 2, 2015 /PRNewswire/ -- Mylan N.V. (Nasdaq: MYL) today announced that the U.S. Patent and Trademark Office (PTO) has instituted an *inter partes* review (IPR) proceeding on all claims against a third Copaxone® 40 mg/mL patent, U.S. Patent No. 8,969,302, owned by Yeda Research & Development Co., Ltd. and licensed to Teva Pharmaceuticals Industries Ltd. The patent relates to methods for the treatment of multiple sclerosis through the administration of at least three 40 mg/mL subcutaneous injections of glatiramer acetate per week.

On Aug. 25, 2015, Mylan announced that the PTO instituted IPR proceedings against two related Copaxone® 40 mg/mL patents, U.S. Patent Nos. 8,232,250 and 8,399,413, on all claims. The oral hearing for all three IPRs has been scheduled for May 12, 2016.

In August 2014, the U.S. Food and Drug Administration accepted Mylan's abbreviated new drug application (ANDA) filing for a three times per week Glatiramer Acetate Injection 40 mg/mL, the generic version of Copaxone 40 mg/mL Mylan believes it is one of 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 in the U.S. upon final FDA approval.

Copaxone 40 mg/mL had U.S. sales of approximately $2.6 billion for the 12 months ending June 30, 2015, according to IMS Health.

This press release includes statements that constitute "forward-looking statements," including with regard to Mylan's belief that it is one of the first companies to have filed a substantially complete ANDA containing a Paragraph IV certification for Glatiramer Acetate Injection 40 mg/mL and that it expects to be eligible for 180 days of marketing exclusivity in the U.S. upon final FDA approval. 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 our introduction of new products; actions taken by regulatory and governmental agencies with respect to our or our competitors' current or future products; success of clinical trials and our ability to execute on new product opportunities; other risks inherent in legal and regulatory processes, 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 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 nearly 50% 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.

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/mylan-confirms-the-us-patent-and-trademark-office-institutes-inter-partes-review-proceeding-against-third-copaxone-40-mgml-dosing-patent-on-all-claims-300136792.html

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