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Mylan Invalidates Two of Teva's Copaxone® 40 mg/mL Patents Via U.S. Patent and Trademark Office's Inter Partes Review Proceeding

HERTFORDSHIRE, England and PITTSBURGH, Aug. 24, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that the U.S. Patent and Trademark Office (PTO) has ruled in favor of Mylan in its *inter partes* review (IPR) proceeding and found all claims of two related Copaxone® 40 mg/mL patents to be unpatentable. The U.S. Patent Nos. are 8,232,250 and 8,399,413, which are owned by Yeda Research & Development Co., Ltd. and licensed to Teva Pharmaceuticals Industries Ltd. A decision by the PTAB on Mylan's third petition seeking *inter partes* review of U.S. Patent No. 8,696,302 is expected on or before September 1, 2016.

On Aug. 15, the PTO's Patent Trial and Appeal Board (PTAB) found Mylan's application against a fourth Copaxone 40 mg/mL patent, U.S. Patent No. 9,155,776, ineligible for post-grant review for procedural reasons. However, Mylan believes that today's favorable ruling in the IPR against the '302 patent strongly undermines the '776 patent as well. As such, Mylan will proceed with pursuing all avenues to challenge the '776 patent.

Mylan CEO Heather Bresch commented, "We believe the Board's decision is comprehensive, well-reasoned, and highly persuasive in detailing the bases for the invalidity of Teva's 40 mg patents, and we look forward to further demonstrating the invalidity of the patents covering Copaxone 40 mg/mL."

Mylan believes it is one of the first companies to have filed a substantially complete abbreviated new drug application containing a Paragraph IV certification for a three times per week Glatiramer Acetate Injection 40 mg/mL, 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 $3.3 billion for the 12 months ending June 30, 2016, 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[; our expectation that the decision on the Copaxone® 40 mg/mL patent, U.S. Patent No. 8,969,302, will be made on or before Sept. 1, 2016; our belief that today's favorable ruling in the IPR against the '302 patent strongly undermines the '776 patent and that Mylan will proceed with challenging the '776 patent in in the District Court and is evaluating a potential IPR challenge; and our belief that the Board's decision is highly persuasive and relevant evidence of the invalidity of Teva's 40 mg patents and that we look forward to further demonstrating the invalidity of these patents in the District Court. 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 more than 2,700 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. Our global R&D and manufacturing platform includes more than 50 facilities, and we are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 40,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com

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