January 30, 2017

Mylan Wins U.S. District Court Ruling Related to Copaxone® 40 mg/mL Patents

HERTFORDSHIRE, England and PITTSBURGH, Jan. 30, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL), today announced the United States District Court for the District of Delaware issued a decision finding all asserted claims of four Orange Book-listed patents relating to Copaxone® 40 mg/mL invalid based on obviousness.

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The invalidated patents are United States Patent Numbers 8,232,250; 8,399,413; 8,969,302; and 9,155,776, which are owned by Yeda Research & Development Co., Ltd. and licensed to Teva Pharmaceuticals Industries, Ltd.

On Dec. 2, 2016, the U.S. Patent and Trademark Office's U.S. Patent Trial and Appeal Board (PTAB) reaffirmed a prior decision that three of these patents ('250, '413 and '302) are unpatentable in its inter partes review (IPR) proceedings initiated by Mylan. Mylan also challenged the '776 patent in an IPR proceeding. The PTAB is expected to issue its institution ruling on the '776 patent IPR by May 16, 2017.

Mylan CEO Heather Bresch commented, "Today's ruling by the U.S. District Court is yet another positive step in our effort to bring to market a more affordable generic version of Copaxone® 40 mg/mL. We will continue to challenge the validity of patents as a way to expedite the availability of generic drugs and help deliver access and savings to patients and the overall healthcare system."

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

Copaxone 40 mg/mL had U.S. sales of approximately $3.3 billion for the 12 months ending Nov. 30, 2016, according to IMS Health.

This press release includes statements that constitute "forward-looking statements," including that Mylan will continue to challenge the validity of patents as a way to expedite the availability of generic drugs and help deliver access and savings to patients and the overall healthcare system; that the PTAB is expected to issue its institution ruling on the '776 patent IPR by May 16, 2017; and that 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. 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 worldwide 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 35,000-strong workforce 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-wins-us-district-court-ruling-related-to-copaxone-40-mgml-patents-300399092.html

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