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Mylan Wins UK Court Ruling Related to Copaxone® 40 mg/mL Patent

HERTFORDSHIRE, England and PITTSBURGH, Oct. 26, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that the United Kingdom's High Court of Justice has issued a decision in favor of Mylan and its European partner Synthon, finding all claims of Teva's patent EP (UK) 2 949 335 (EP 335) relating to Copaxone® 40 mg/mL invalid based on obviousness.

This victory is yet another important milestone for Mylan, and this U.K. court decision only further increases Mylan's confidence in its ability to bring high quality, lower-cost generic versions of Copaxone to the multiple sclerosis community and patients around the world.

Over the course of the last eight years, Mylan has successfully overcome Teva's four waves of U.S. patent litigation, eight Citizen Petitions, injunction proceedings in India, more than 15 regulatory challenges, patent litigations or commercial actions across Europe, and now the litigation in the U.K., in addition to obtaining dismissal of Teva's suit against the FDA seeking to delay approval of the 20 mg/mL product. Today's positive ruling in the U.K. will further help pave the way for Mylan's future launches of Glatiramer Acetate Injection 40 mg/mL in certain European markets.

In addition, Mylan recently learned of Teva's latest action with the filing of an infringement action against Mylan's Irish subsidiary Mylan Teoranta in the High Court of Ireland alleging that Mylan's Glatiramer Acetate 40 mg/mL injection infringes two European patents. In fact, one of those patents is the same patent that was just invalidated today by the U.K. High Court of Justice and the counterpart to a U.S. patent that was previously held invalid by both the United States District Court for the District of Delaware and the Patent Trial and Appeal Board.

Mylan will support the multiple sclerosis patient population through its continued commitment to bring lower-cost generic versions of Copaxone around the world regardless of any further attempts by Teva to deny such access.

Glatiramer Acetate Injection 40 mg/mL in the U.S.
In early October, Mylan received FDA approval and launched its Glatiramer Acetate Injection 40 mg/mL for 3-times-a-week injection, an AP-rated, substitutable generic version of Teva's Copaxone 40 mg/mL. According to the FDA approval letter, Mylan was one of the first applicants to submit a substantially complete Abbreviated New Drug Application for Glatiramer Acetate Injection, 40 mg/mL, containing a Paragraph IV certification.

Glatiramer Acetate Injection 40 mg/mL in Europe
In Europe, Mylan is partnered with Synthon, the developer and supplier of its European Glatiramer Acetate Injection 40 mg/mL product, and has exclusive distribution and supply rights for the U.K. as well as Germany, France, Spain, Portugal, Belgium, Italy, the Netherlands, Republic of Ireland, Switzerland, Greece, Denmark, Sweden, Norway, Finland, Cyprus and Malta. On Oct. 5, Synthon received marketing authorization approval in Europe for its Glatiramer Acetate Injection 40 mg/mL product.

This press release includes statements that constitute "forward-looking statements," including with regard to: the launch of Mylan's Glatiramer Acetate Injection products; Mylan's efforts to bring high quality, lower-cost generic versions of Copaxone to market around the world; that today's positive ruling in the U.K will further help pave the way for Mylan's future launches of Glatiramer Acetate Injection 40 mg/mL in certain European markets; that Mylan is supporting the multiple sclerosis patient population through its continued commitment to bring its lower-cost generic versions of Copaxone regardless of any further attempts by Teva to deny such access. 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: changes in healthcare and pharmaceutical laws and regulations in the U.S. and abroad; actions and decisions of healthcare and pharmaceutical regulators; determinations by health insurance companies regarding coverage for Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL; any regulatory, legal, or other impediments to Mylan's ability to bring Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL to market, including ongoing and unresolved allegations of patent infringement around our launch of Glatiramer Acetate Injection 40 mg/mL; any changes in or difficulties with Mylan's or its partners' inventory of, and ability to manufacture and distribute, Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL to meet anticipated demand; the potential impact of any change in patient access to or demand for Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL; the scope, timing, and outcome of any ongoing legal proceedings, including but not limited to government investigations, and the impact of any such proceedings on Mylan's or its partners' business; the impact of competition; strategies by competitors or other third parties to delay or prevent product introductions, including Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL; changes in the economic and financial conditions of the businesses of Mylan or its partners; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update any statements herein for revisions or changes after the date of this release.

About Mylan
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 7,500 marketed products around the world, 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. 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.

Copaxone® is a registered trademark of Teva Pharmaceutical Industries Ltd.

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