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## Mylan, in Partnership with Synthon, Receives Marketing Authorization Approval in Europe for First Generic for Copaxone® 40 mg/mL

## Mylan Has Exclusive Rights for Glatiramer Acetate in Several Key European Markets

HERTFORDSHIRE, England and PITTSBURGH, Oct. 5, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that partner, Synthon, received marketing authorization approval in Europe for Glatiramer Acetate Injection 40 mg/mL, a therapeutically equivalent generic version of Teva's Copaxone<sup>®</sup> 40 mg/mL, indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), a chronic inflammatory disease of the central nervous system.



This approval complements last year's approval of Glatiramer Acetate Injection 20 mg/mL, which already is available in several European markets.

Granting of national marketing authorizations is expected to follow in the near future.

Mylan CEO Heather Bresch commented, "We're pleased with the approval of Glatiramer Acetate Injection 40 mg/mL, and look forward to leading the marketing and selling of this important product in our European markets. Mylan recognizes the complexities of MS care and challenges faced by patients. This approval reinforces our commitment to helping patients and healthcare providers by providing alternative treatment options to better serve the needs of this community. The approval also highlights Mylan's commercial capabilities and ability to commercialize complex products around the globe."

Mylan is partnered with Synthon, the developer and supplier of its European Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL products, and has exclusive distribution and supply rights for the products for Germany, France, Spain, Portugal, Belgium, Italy, the Netherlands, United Kingdom, Republic of Ireland, Switzerland, Greece, Denmark, Sweden, Norway, Finland, Cyprus and Malta.

## **Forward-Looking Statements**

This press release includes statements that constitute "forward-looking statements," including with regard to bringing Glatiramer Acetate Injection 40 mg/mL product to market, that Mylan looks forward to leading the marketing and selling of this important product in its European markets and that the granting of national marketing authorizations is expected to follow in the near future. 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 40 mg/mL; any regulatory, legal, or other impediments to Mylan's ability to bring Glatiramer Acetate Injection 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; 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.

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