Mylan and Development Partner, Synthon, Win Significant European Patent Office Ruling Related to Copaxone® 40mg/mL

September 15, 2020

Decision clears legal pathway to expand access for patients living with multiple sclerosis in markets across Europe

HERTFORDSHIRE, England and PITTSBURGH, Sept. 15, 2020 /PRNewswire/ -- Mylan N.V. (NASDAQ: MYL) today announced that the Technical Board of Appeal of the European Patent Office (EPO) has held that Yeda Research and Development Company, Ltd.'s European Patent no. 2 949 335 related to Teva's Copaxone® 40 mg/mL three times weekly product is invalid and revoked across Europe.

With the EPO's decision, Mylan has once again overcome Teva's attempts to restrict MS patients' access to safe and affordable alternatives. Over the course of the last eleven years, Mylan has successfully defeated Teva's four waves of U.S. patent litigation, eight Citizen Petitions, injunction proceedings in India, and more than 15 regulatory challenges, patent litigations or commercial actions across Europe. The EPO's positive ruling will allow Mylan to immediately return to the market and accelerate commercialization in other markets across Europe.

Mylan CEO Heather Bresch commented: "There are many ways in which we demonstrate our commitment to expand access to medicine, including by leveraging our legal expertise to overcome barriers on behalf of the patients we serve. The decision by the EPO marks a significant step forward for Mylan in several ongoing legal actions around Europe related to this important product, and further increases our confidence in our ability to continue to expand access to a lower-cost, high quality, therapeutically equivalent version of Copaxone to the multiple sclerosis community across even more markets in Europe and beyond."

Indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), a chronic inflammatory disease of the central nervous system, Mylan's lower-cost therapeutically equivalent version of Copaxone® will benefit thousands of MS patients across Europe who are living with this very difficult condition and in need of a more affordable treatment option. Mylan's product is currently marketed under a number of brand names in European markets including Brabio, Clift, Copemyl, Copemyltri and Glatiramyl.

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 portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally 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 approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements," including with regard to the outcome of litigation; the decision further clears legal pathway to expand access for patients living with multiple sclerosis in markets across Europe; the EPO's positive ruling will allow Mylan to immediately return to the market and accelerate commercialization in other markets across Europe; and the decision by the EPO marks a significant step forward for Mylan in several ongoing legal actions around Europe related to this important product, and further increases our confidence in our ability to continue to expand access to a lower-cost, high quality, therapeutically equivalent version of Copaxone to the multiple sclerosis community across even more markets in Europe and beyond. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to the potential widespread and highly uncertain impact of public health outbreaks, epidemics and pandemics, such as the COVID-19 pandemic; any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; risks associated with international operations; 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 these statements for revisions or changes after the date of this release.

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