October 3, 2017

Mylan Announces U.S. FDA Approval of First Generic for Copaxone® 40 mg/mL 3-Times-a-Week and May Be Eligible for 180-Day Exclusivity

Mylan Also Receives U.S. FDA Approval of Generic for Copaxone® 20 mg/mL Once-Daily

HERTFORDSHIRE, England, and PITTSBURGH, Oct. 3, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that the U.S. Food and Drug Administration (FDA) has approved Mylan's Abbreviated New Drug Applications (ANDAs) for 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, and Glatiramer Acetate Injection 20 mg/mL for once-daily injection, an AP-rated, substitutable generic version of Teva's Copaxone® 20 mg/mL, which are indicated for the treatment of patients with relapsing forms of multiple sclerosis (MS), a chronic inflammatory disease of the central nervous system. Mylan will begin shipping imminently.

"The FDA approvals of Mylan's Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL as AP-rated, substitutable generics for Copaxone® 20 mg/mL and 40 mg/mL, respectively, mark another significant milestone for our company, reinforce our proven capabilities in bringing complex and difficult-to-manufacture products to market, and further our commitment to providing access to high quality medicines," said Mylan CEO Heather Bresch. "Mylan has invested tens of millions of dollars over many years to bring this important medicine to market. Providing patients, healthcare providers and caregivers with treatment options is very important when it comes to selecting the right therapy for relapsing forms of multiple sclerosis. Our commitment to the MS patient community extends beyond bringing generic versions of these products to market. Mylan also is offering comprehensive patient support services to help patients access therapy as quickly as possible and adhere to a treatment regimen that fits their needs."

The FDA approved Mylan's Glatiramer Acetate Injection 40 mg/mL for 3-times-a-week injection and 20 mg/mL for once-daily injection as therapeutic AP-rated equivalents to Copaxone® 40 mg/mL and Copaxone® 20 mg/mL, respectively, meaning if they are substituted for their branded counterpart they can be expected to have the same clinical effect and safety profile. As part of its ANDAs, Mylan submitted rigorous side-by-side analyses, including characterization data, which demonstrated that Mylan's Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL have the same active ingredient, dosage form, route of administration and strength as their branded counterpart. Mylan's Glatiramer Acetate Injection 20 mg/mL and 40 mg/mL are available by prescription only.

According to the FDA approval letter, Mylan was one of the first applicants to submit a substantially complete ANDA for Glatiramer Acetate Injection, 40 mg/mL, containing a Paragraph IV certification. Therefore, Mylan and other first filers may be eligible for 180 days of generic drug exclusivity but FDA has not made a formal determination on exclusivity at this time.

In addition, Mylan is introducing Mylan MS Advocate™, a comprehensive patient support service program to help patients get started on and stay on track with their physician's treatment plan for either dose strength of Mylan's Glatiramer Acetate Injection. All patients prescribed and taking Mylan's Glatiramer Acetate Injection 3-times-a-week 40 mg/mL or once-daily 20 mg/mL are eligible to enroll in the program which includes an interactive mobile app, in-home injection training, a 24/7 patient support center, co-pay assistance for eligible patients and ongoing support from an MS-experienced nurse.

Copaxone® is the most prescribed MS treatment for relapsing forms of MS in the United States with brand sales for the 20 mg/mL dose of approximately $700 million and for the 40 mg/mL dose of approximately $3.64 billion for the 12 months ending July 31, 2017, according to QuintilesIMS. Approximately 400,000 individuals in the U.S. have MS and relapsing MS accounts for 85% of initial MS diagnoses.

Currently, Mylan has 225 ANDAs pending FDA approval representing approximately $92.5 billion in annual brand sales, according to QuintilesIMS. Forty-four of these pending ANDAs are potential first-to-file opportunities, representing $41.9 billion in annual brand sales, for the 12 months ending July 31, 2017, according to QuintilesIMS. Currently, one out of every 13 prescriptions filled in the U.S. - brand-name or generic - is a Mylan product.

INDICATION

GLATIRAMER ACETATE INJECTION is a prescription medicine used for the treatment of people with relapsing forms of multiple sclerosis (MS).

IMPORTANT SAFETY INFORMATION

Do not take GLATIRAMER ACETATE INJECTION if you are allergic to glatiramer acetate or mannitol.

Some patients report a short-term reaction right after injecting glatiramer acetate. This reaction can involve flushing (feeling of warmth and/or redness), chest tightness or pain with heart palpitations, anxiety, and trouble breathing. These symptoms generally appear within minutes of an injection, last about 15 minutes, and do not require specific treatment. There have been reports of patients with similar symptoms who received emergency medical care. **If symptoms become severe, call the emergency phone numbers in your area.**

Call your doctor right away if you develop hives, skin rash with irritation, dizziness, sweating, chest pain, trouble breathing, or severe pain at the injection site. If any of the above occurs, do not give yourself any more injections until your doctor tells you to begin again.

Chest pain may occur either as part of the immediate post-injection reaction or on its own. This pain should only last a few minutes. You may experience more than one such episode, usually beginning at least one month after starting treatment. Tell your doctor if you experience chest pain that lasts for a long time or feels very intense.

A permanent indentation under the skin (lipoatrophy and, rarely, death of your skin tissue also referred to as necrosis) at the injection site may occur due to local destruction of fat tissue. Be sure to follow proper injection technique and inform your doctor of any skin changes.

The most common side effects in studies of GLATIRAMER ACETATE INJECTION are redness, pain, swelling, itching, or a lump at the site of injection, flushing, rash, shortness of breath, and chest pain. These are not all of the possible side effects of GLATIRAMER ACETATE INJECTION. For a complete list, ask your doctor or pharmacist. Tell your doctor about any side effects that you have while taking GLATIRAMER ACETATE INJECTION.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information, Patient Information Leaflet, and Instructions for Use for GLATIRAMER ACETATE INJECTION.

About the Abbreviated New Drug Application (ANDA) Process

The U.S. Food and Drug Administration (FDA) requires generic medications to have the same active ingredient, strength, purity and identity, among other characteristics, as the branded reference medication. Companies compile this information, based on extensive testing, in an Abbreviated New Drug Application (ANDA) and share it with FDA for review. An A-rated generic is determined by the FDA to be interchangeable with the branded version. Generic medications comprised 89% of prescriptions dispensed in the U.S. in 2016.

Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements," including with regard to the launch of Mylan's Glatiramer Acetate Injection products, and that Mylan and other first filers may be eligible for 180 days of generic drug exclusivity with respect to Glatiramer Acetate Injection 40 mg/mL, and that Mylan will begin shipping Glatiramer Acetate Injection products imminently, and the introduction of Mylan MS Advocate™, a comprehensive patient support service program to help patients get started on and stay on track with their physician's treatment plan for either dose strength of Mylan's Glatiramer Acetate Injection, including an interactive mobile app, in-home injection training, a 24/7 patient support center, co-pay assistance for eligible patients and ongoing support from an MS-experienced nurse. 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; potential forfeiture of exclusivity periods for failure to obtain tentative approval; 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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