Pfizer Logo

Pfizer and Synthon Enter Into U.S. Commercialization Agreement for Potential Generic Treatment of Multiple Sclerosis

Monday, August 03, 2015 - 04:30am

Synthon’s glatiramer acetate, a potential generic version of Copaxone®1 for the treatment of relapsing remitting multiple sclerosis is currently being reviewed by the U.S. Food and Drug Administration

“Pfizer’s significant experience in successfully bringing meaningful medicines to market together with Synthon’s scientific expertise in neurodegenerative diseases will enable us to leverage our core capabilities in support of improving patient health in the United States.”

Pfizer Inc. and Synthon, an international pharmaceutical company specializing in the development of complex generic medicines, today announced they have entered into an agreement whereby Pfizer has acquired the exclusive commercialization rights in the United States to glatiramer acetate, a potential generic version of the originator medicine Copaxone® for the treatment of relapsing remitting multiple sclerosis (RRMS).

In November 2011, Synthon filed an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) for a once daily 20mg/ml formulation of glatiramer acetate. In early 2014, Synthon filed an ANDA for a three times a week 40mg/ml formulation of glatiramer acetate with the FDA. In addition, Synthon believes its glatiramer acetate 40mg/ml filing may be eligible for 180 days of shared marketing exclusivity under the provisions of the Hatch-Waxman Act.

“Neurologic diseases such as multiple sclerosis represent some of the most debilitating illnesses of our time,” said Diem Nguyen, regional president of North America, Pfizer Global Established Pharma business. “Pfizer’s significant experience in successfully bringing meaningful medicines to market together with Synthon’s scientific expertise in neurodegenerative diseases will enable us to leverage our core capabilities in support of improving patient health in the United States.”

Under the terms of the agreement, Pfizer will have exclusive rights to commercialize both dosage formulations of Synthon’s glatiramer acetate in the United States. Synthon is responsible for the clinical development, manufacture and supply of glatiramer acetate. Pfizer is solely responsible for the commercialization of glatiramer acetate in the United States. Financial terms of the agreement were not disclosed.

“We are very pleased to partner with Pfizer on the introduction of glatiramer acetate to patients and healthcare providers in the United States,” said Jacques Lemmens, chief executive officer of Synthon. “Our partnership will ensure the rapid introduction of a high quality product through Pfizer’s well-established presence in the United States, which in turn may result in savings on an important MS medication for patients and payors.”

About GATE:

A Phase III Glatiramer Acetate clinical trial To assess Equivalence with Copaxone® (GATE) was set up following Scientific Advice received from the European Medicines Agency (EMA) with the aim to show equivalence of Synthon's glatiramer acetate (Synthon GTR) with Teva's Copaxone® in a well-controlled 3-arm double-blind equivalence study. The open-label part of the study further aimed to provide 2-year efficacy, safety and tolerability data on Synthon's generic glatiramer acetate and to show safety of switching from Copaxone® to Synthon's generic. The large-scale, multicenter study consisted of a nine-month double-blind efficacy comparison followed by a 15-month open-label extension and was executed in RRMS patients in Europe (including Russia, Ukraine and Belarus), Mexico, South Africa and the United States.

About Multiple Sclerosis: Multiple sclerosis (MS) is an unpredictable, often disabling disease of the central nervous system which interrupts the flow of information within the brain, and between the brain and body. Signs and symptoms vary widely, depending upon the amount of damage and which nerves are affected. Symptoms range from numbness and tingling to blindness and paralysis. These problems may come and go or persist and worsen over time. Relapsing Remitting Multiple Sclerosis (RRMS) is the most common form of MS characterized by clear episodes of inflammatory activity known as relapses, followed by remission. RRMS affects approximately 85 percent of newly diagnosed patients.

According to the National Multiple Sclerosis Society, most people with MS are diagnosed between the ages of 20 years and 50 years, with at least two to three times more women than men being diagnosed with the disease. MS affects more than 2.3 million people worldwide. In the United States, the number of people with MS is estimated to be about 400,000.

About Synthon:

Synthon, with headquarters in Nijmegen, the Netherlands, is an international pharmaceutical company and a leader in the field of complex generic medicines. The company started its biopharmaceutical franchise in 2007 and is building a promising portfolio of next generation medicines. Synthon is developing rapidly into a specialty pharmaceutical company, focusing on the therapeutic areas of auto-immune diseases and oncology. Synthon products are currently approved by regulatory agencies in over 90 countries worldwide and marketed through strategic partnerships and – in dedicated areas – through direct sales. Synthon employs about 1,500 staff worldwide, and in 2014 it recorded a turnover of EUR 218 million. For more information, go to www.synthon.com.

Pfizer Inc.: Working together for a healthier world™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety, and value in the discovery, development, and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments, and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments, and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: The information contained in this release is as of August 3, 2015. Synthon and Pfizer assume no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information regarding Synthon's potential generic version of Copaxone, glatiramer acetate, and an agreement between Synthon and Pfizer for the commercialization of glatiramer acetate once daily 20m/ml and three times a week 40mg/ml dosages formulations in the United States that involves substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including whether and when applications with the FDA may be approved, which will depend on the assessment by the FDA of Synthon's ANDA submission and related documentation; decisions by the FDA regarding labeling and other matters that could affect the availability or commercial potential of glatiramer acetate; the ability to successfully commercialize such products in the United States; and competitive developments.

A further description of risks and uncertainties related to Pfizer can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results", as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com

1 Copaxone® is a registered trademark of Teva Pharmaceuticals Industry Ltd.

Pfizer Media: Mackay Jimeson, 212-733-2324 or Pfizer Investor: Ryan Crowe, 212-733-8160 or Synthon: Fabienne Douven, 31(0)24 37 27 700