



Pharmaceuticals

## NEWS RELEASE

### TEVA ANNOUNCES U.S. FDA APPROVAL OF THREE-TIMES-A-WEEK COPAXONE® (GLATIRAMER ACETATE INJECTION) 40MG/ML

*New Formulation of COPAXONE® Offers Patients and Their Physicians Ability to Dose Less Frequently*

JERUSALEM--(BUSINESS WIRE)--Jan. 28, 2014-- Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) announced today that the U.S. Food and Drug Administration (FDA) has approved the Company's supplemental new drug application (sNDA) for three-times-a-week COPAXONE® 40mg/mL, a new dose of COPAXONE®. This new formulation will allow for a less frequent dosing regimen administered subcutaneously for patients with relapsing forms of multiple sclerosis (MS). In addition to the newly approved dose, daily COPAXONE® 20 mg/mL will continue to be available. The daily subcutaneous injection was approved in 1996.

"The availability of three-times-a-week COPAXONE® 40 mg/mL is a significant advancement for patients as they now have the option of effective and safe treatment with COPAXONE®, while reducing the number of injections by 60 percent," said Omar Khan, M.D., Professor of Neurology and Chair of the Department of Neurology, Wayne State University School of Medicine, Detroit, MI. "Patients in the U.S. can now benefit from an improved dosing regimen without compromising the known benefits of COPAXONE®."

The FDA approval is based on data from the Phase III Glatiramer Acetate Low-Frequency Administration (GALA) study of more than 1400 patients, which showed that a 40 mg/mL dose of COPAXONE® administered subcutaneously three-times-a-week significantly reduced relapse rates at 12 months and demonstrated a favorable safety and tolerability profile in patients with relapsing-remitting MS.

"For more than 20 years, Teva has pursued its multiple sclerosis research with the goal of providing effective, safe and tolerable therapies for MS patients," said Larry Downey, President, North America Specialty Medicines. "We have progressively invested in the innovation of COPAXONE® in an effort to understand the needs and to ease the burden of patients who live with relapsing forms of MS every day. Today we are proud to continue to deliver on that investment by offering the freedom to dose three-times-a-week with COPAXONE® 40 mg/mL."

Three-times-a-week COPAXONE® 40mg/mL is available for shipping to distribution outlets immediately, and will be available to patients within days. Teva's Shared Solutions® patient support center has been scaled to support current patients as they transition to the new, three-times-a-week 40mg/mL formulation. Patients may call their doctors or Teva's Shared Solutions® (1-800-887-8100) and make a request. In addition, Shared Solutions® provides 24/7 nurse support, financial and benefits investigation as well as identification of pharmacy distribution options to enable financial and physical access to COPAXONE®. Shared Solutions also provides free injection training as well as ongoing compliance and adherence support services.

#### About COPAXONE®

COPAXONE® (glatiramer acetate injection) is indicated for the treatment of patients with relapsing forms of multiple sclerosis. The most common side effects of COPAXONE® are redness, pain, swelling, itching, or a



prescribing information. COPAXONE<sup>®</sup> is now approved in more than 50 countries worldwide, including the United States, Russia, Canada, Mexico, Australia, Israel, and all European countries.

### Important Safety Information about COPAXONE<sup>®</sup>

Patients allergic to glatiramer acetate or mannitol should not take COPAXONE<sup>®</sup>. Some patients report a short-term reaction right after injecting COPAXONE<sup>®</sup>. 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 go away by themselves without further problems. During the postmarketing period, there have been reports of patients with similar symptoms who received emergency medical care. **If symptoms become severe, patients should call the emergency phone number in their area.** Patients should call their doctor right away if they 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, patients should not give themselves any more injections until their doctor tells them to begin again. Chest pain may occur either as part of the immediate postinjection reaction or on its own. This pain should only last a few minutes. Patients may experience more than one such episode, usually beginning at least one month after starting treatment. Patients should tell their doctor if they experience chest pain that lasts for a long time or feels very intense. A permanent indentation under the skin (lipoatrophy or, rarely, necrosis) at the injection site may occur, due to local destruction of fat tissue. Patients should follow proper injection technique and inform their doctor of any skin changes. The most common side effects of COPAXONE<sup>®</sup> 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 COPAXONE<sup>®</sup>. For a complete list, patients should ask their doctor or pharmacist. Patients should tell their doctor about any side effects they have while taking COPAXONE<sup>®</sup>.

Patients are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

### About Teva

Teva Pharmaceutical Industries Ltd. (NYSE: TEVA) is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's leading generic drug maker, with a global product portfolio of more than 1,000 molecules and a direct presence in about 60 countries. Teva's branded businesses focus on CNS, oncology, pain, respiratory and women's health therapeutic areas as well as biologics. Teva currently employs approximately 46,000 people around the world and reached \$20.3 billion in net revenues in 2012.

**Teva's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:** *The following presentation contains forward-looking statements, which express the current beliefs and expectations of management. Such statements involve a number of known and unknown risks and uncertainties that could cause our future results, performance or achievements to differ significantly from the results, performance or achievements expressed or implied by such forward-looking statements. Important factors that could cause or contribute to such differences include risks relating to: our ability to develop and commercialize additional pharmaceutical products, competition for our innovative medicines, especially Copaxone<sup>®</sup> (including competition from innovative orally-administered alternatives, as well as from potential purported generic equivalents), competition for our generic products (including from other pharmaceutical companies and as a result of increased governmental pricing pressures), competition for our specialty pharmaceutical businesses, our ability to achieve expected results through our specialty, including innovative, R&D efforts, the effectiveness of our patents and other protections for innovative products, decreasing opportunities to obtain U.S. market exclusivity for significant new generic products, our ability to identify, consummate and successfully integrate acquisitions and license products, our ability to reduce operating expenses to the extent and during the timeframe intended by our cost restructuring program, uncertainties relating to the replacement of and transition to a new President & Chief Executive Officer, the effects of increased leverage as a result of recent acquisitions, the extent to which any manufacturing or quality control problems damage our reputation for high quality production and require costly remediation, our potential exposure to product liability claims to the extent not covered by insurance, increased government scrutiny in both the U.S. and Europe of our settlement agreements with brand companies and liabilities arising from*



*fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement, any failures to comply with complex Medicare and Medicaid reporting and payment obligations, governmental investigations into sales and marketing practices, particularly for our specialty medicines (and our ongoing FCPA investigations and related matters), uncertainties surrounding the legislative and regulatory pathways for the registration and approval of biotechnology-based medicines, adverse effects of political or economic instability, corruption, major hostilities or acts of terrorism on our significant worldwide operations, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, any failure to retain key personnel or to attract additional executive and managerial talent, the impact of continuing consolidation of our distributors and customers, variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, the termination or expiration of governmental programs or tax benefits, environmental risks, and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2012 and in our other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and the Company undertakes no obligation to update or revise any forward looking statement, whether as a result of new information, future events or otherwise.*

Source: Teva Pharmaceutical Industries Ltd.

Teva Pharmaceutical Industries Ltd.

IR Contacts:

United States

Kevin C. Mannix, (215) 591-8912

Ran Meir, (215) 591-3033

Israel

Tomer Amitai, 972 (3) 926-7656

or

PR Contacts:

Israel

Iris Beck Codner, 972 (3) 926-7687

United States

Denise Bradley, (215) 591-8974

Nancy Leone, (215) 284-0213