TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
June 02, 2011

**FORM 6-K**

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**Report of Foreign Private Issuer**

**Pursuant to Rule 13a 16 or 15d 16**

**under the Securities Exchange Act of 1934**

For the month of June 2011

Commission File Number 0-16174

**Teva Pharmaceutical Industries Limited**

(Translation of registrant's name into English)

**5 Basel Street, P.O. Box 3190**

**Petach Tikva 49131 Israel**

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F X Form 40-F _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

**Teva Completes Enrollment in Phase III Multiple Sclerosis Trial**

**Evaluating Glatiramer Acetate Three Times Weekly**

**Jerusalem, June 2, 2011** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced completion of patient enrollment for the GALA (Glatiramer Acetate Low-frequency Administration) trial. This international Phase III trial in patients with relapsing-remitting multiple sclerosis (RRMS), is designed to examine the efficacy, safety and tolerability of 40mg COPAXONE&reg (glatiramer acetate injection) administered three times a week compared to placebo. The primary endpoint of the trial is the total number of confirmed relapses during a 12-month placebo-controlled phase, which will be followed by an open-label extension phase.

Patient enrollment was completed in May 2011, recruiting over 1,400 patients at 180 sites in the United States, Europe, Central Eastern Europe and Israel. Results from the trial are expected in the second quarter of 2012.

"The GALA trial demonstrates Teva`s commitment to the continued research and development of COPAXONE&reg, the global-leading RRMS therapy with 20 years of robust efficacy and safety data," said **Professor Yitzhak Peterburg, Teva's Group Vice President, Global Branded Products**. "With glatiramer acetate 40mg three times a week, we hope to further enhance the patient experience over the long-term."

The GALA study investigates glatiramer acetate 40mg administered three times a week in comparison to placebo. This dose (glatiramer acetate 40mg) is a higher strength than the currently marketed 20mg of COPAXONE&reg injected daily.

COPAXONE&reg is currently approved in over 50 countries worldwide and is indicated for the treatment of RRMS and for patients presenting with clinically isolated syndrome (CIS). It is the worldwide market-leading RRMS treatment with a global market share of 31%.

**ABOUT MULTIPLE SCLEROSIS (MS)**

MS is a chronic, often disabling disease that attacks the central nervous system. Symptoms may be mild, such as numbness in the limbs, or severe, such as paralysis or loss of vision. The progress, severity, and specific symptoms of MS are unpredictable and vary from one person to another. In the U.S. today, there are approximately 400,000 people with MS - with 200 more people diagnosed every week. Worldwide, MS is thought to affect more than 2.1 million people.

**ABOUT COPAXONE**&reg

COPAXONE&reg is indicated for the reduction of the frequency of relapses in relapsing-remitting multiple sclerosis, including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. The most common side effects of COPAXONE&reg are redness, pain, swelling, itching, or a lump at the site of injection, flushing, rash, shortness of breath, and chest pain. COPAXONE&reg (glatiramer acetate injection) is now approved in more than 50 countries worldwide, including the United States, Russia, Canada, Mexico, Australia, Israel, and all European countries. In North America, COPAXONE&reg is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva Pharmaceutical Industries Ltd. In Europe, COPAXONE&reg is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. COPAXONE&reg is a registered trademark of Teva Pharmaceutical Industries Ltd.

See additional important information at: http://www.sharedsolutions.com/pdfs/PrescribingInformation.aspx or call 1-800-887-8100 for electronic releases.

**ABOUT TEVA**

Teva Pharmaceutical Industries Ltd. (Nasdaq: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 largest generic drug maker, with a global product portfolio of more than 1,450 molecules and a direct presence in about 60 countries. Teva's branded businesses focus on neurological, respiratory and women's health therapeutic areas as well as biologics. Teva's leading innovative product, COPAXONE&reg, is the number one prescribed treatment for relapsing-remitting multiple sclerosis. Teva employs approximately 40,000 people around the world and reached $16.1 billion in net sales in 2010.

**Teva's Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995:**

*This release contains forward-looking statements, which express the current beliefs and expectations of management. Such statements are based on management's current beliefs and expectations and 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 from the introduction of competing generic equivalents and due to increased governmental pricing pressures, the effects of competition on sales of our innovative products, especially COPAXONE® (including competition from innovative orally-administered alternatives as well as from potential generic equivalents), potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Neurontin®, Lotrel® and Protonix®, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products, the extent to which any manufacturing or quality control problems damage our reputation for high quality production and require costly remediation, our ability to identify, consummate and successfully integrate acquisitions (including the pending acquisition of Cephalon and Taiyo), our ability to achieve expected results through our innovative R&D efforts, dependence on the effectiveness of our patents and other protections for innovative products, intense competition in our specialty pharmaceutical businesses, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, our potential exposure to product liability claims to the extent not covered by insurance, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation and pharmaceutical pricing and reimbursement, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, the impact of continuing consolidation of our distributors and customers, the difficulty of complying with U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority requirements, 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, any failure to retain key personnel or to attract additional executive and managerial talent, environmental risks and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission.*

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Website: **www.tevapharm.com**

Teva Pharmaceutical Industries Ltd. Web Site: www.tevapharm.com

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TEVA PHARMACEUTICAL INDUSTRIES LIMITED

(Registrant)

By: /s/ Eyal Desheh

Name: Eyal Desheh
Title: Chief Financial Officer

Date: June 2, 2011