

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
October 11, 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 October 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): _____

Significant Reduced Loss of Brain Volume in Multiple Sclerosis Patients Treated with COPAXONE®

Five-year Study Findings Published in the *Journal of the Neurological Sciences*

JERUSALEM, Israel--(BUSINESS WIRE)--October 11, 2011--Results from a five-year study of treatment-naïve patients with relapsing-remitting multiple sclerosis (RRMS) demonstrated that patients treated with COPAXONE® (glatiramer acetate injection) showed significant reduced loss of brain volume compared to patients treated with other disease modifying therapies (DMTs).

Though all DMT treatment arms resulted in a reduction in brain volume loss compared to the control group of non-treated patients, COPAXONE® had a significantly better effect than both low and high dose interferons, in reducing loss of brain volume. A paper published by Dr. Omar Khan, detailing the study findings, “Effect of disease-modifying therapies on brain volume in relapsing–remitting multiple sclerosis: Results of a five-year brain MRI study,” was recently published in the *Journal of the Neurological Sciences*.

“These data represent the importance of ongoing research in a practical clinical setting to better understand multiple sclerosis and the impact of therapy on the course of the disease ,” said Jon Congleton, Senior Vice President and General Manager, Teva Neuroscience. “Not only does this study highlight the benefit of COPAXONE® in reducing brain volume loss, it underscores the value of early treatment in influencing long-term outcomes.”

Brain volume loss in multiple sclerosis patients exceeds the rate of healthy control groups. Brain volume loss, sometimes referred to as atrophy, may be correlated with cognitive and physical deficits. Modern magnetic resonance (MR) techniques can reliably measure loss of brain volume over time.

ABOUT THE STUDY

In the study, the COPAXONE® treatment arm resulted in a -2.27 percent change in brain volume (PCVB) as compared to baseline versus -2.62 percent for Avonex® (low-dose interferon), -3.21 percent for Betaseron®/Rebif® (high-dose interferon).

This was a retrospective study in which the brain magnetic resonance imaging (MRI) scans of 275 RRMS patients treated with DMTs were examined with Structural Image Evaluation, using Normalization of Atrophy (SIENA). Data analysis was conducted in 2007-08 and the study period included patients who started DMTs in 2001-02 and subsequently received the same DMT for five years. Inclusion criteria for the study were diagnosis of clinically definite RRMS, disease duration of five years or less at the time of initiating DMT and treatment-naïve prior to initiation of DMT at onset of study observation period. Untreated RRMS patients with follow-up ranging from eight to 24 months were enrolled as controls. All untreated patients also had prior brain MRI scans on no therapy that could be analyzed with SIENA, so that their rate of brain volume loss was annualized and then projected over five years assuming a constant rate of brain volume loss over five years.

121 patients in the study were treated with COPAXONE®, 101 were treated with Betaseron® or Rebif® and 53 were treated with Avonex®. All patients had brain MRI scans (at onset of DMT and five years later) on the same 1.5T scanner. Image analysis was performed blinded to treatment allocation.

The study was supported by Wayne State University Neuroscience Program. Preliminary results from this study were presented at the American Academy of Neurology annual meeting in 2008.

ABOUT COPAXONE®

COPAXONE® 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® are redness, pain, swelling, itching, or a lump at the site of injection, flushing, rash, shortness of breath, and chest pain. COPAXONE® (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® is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva Pharmaceutical Industries Ltd. In Europe, COPAXONE® is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. COPAXONE® 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 1,300 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 currently employs approximately 42,000 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 successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products and regulatory changes that may prevent us from utilizing exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic version of Protonix®, the extent to which any manufacturing or quality control problems damage our reputation for high quality production, the effects of competition on sales of our innovative products, especially Copaxone® (including potential generic and oral competition for Copaxone®), the impact of continuing consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of Cephalon), interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, intense competition in our specialty pharmaceutical businesses, 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, 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, dependence on the effectiveness of our patents and other protections for innovative products, our ability to achieve expected results through our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, potentially significant

impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, our potential exposure to product liability claims to the extent not covered by insurance, the termination or expiration of governmental programs or tax benefits, current economic conditions, any failure to retain key personnel or to attract additional executive and managerial talent, environmental risks and other factors that are discussed in our Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission.

CONTACT:

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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: October 11, 2011