

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
October 23, 2007

**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 2007

Commission File Number 0-16174



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**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

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):

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes

No

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b):  
82- \_\_\_\_\_



Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://www.tevapharm.com)

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For Immediate Release

**COPAXONE<sup>®</sup> SIGNIFICANTLY DECREASES DISEASE ACTIVITY IN PATIENTS WHO SWITCHED FROM INTERFERON BETA (IFN $\beta$ ) DUE TO DEVELOPMENT OF NEUTRALIZING ANTIBODIES (NAbs)**

*Relapsing-remitting multiple sclerosis Patients Experience Significantly Extended Time to First Relapse Compared to NAbs-Positive IFN $\beta$  Patients*

**Jerusalem, Israel, October 23, 2007** - Patients treated with interferon beta (IFN $\beta$ ) who have experienced loss of efficacy due to the development of neutralizing antibodies, had a significant delay in time to first relapse ( $p=0.0389$ ) following switch to COPAXONE<sup>®</sup>. In addition, patients who were switched to COPAXONE<sup>®</sup> experienced reduction in mean annual relapse rate compared to Pre IFN $\beta$  treatment. Results from this retrospective comparative study were presented at the 23rd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Prague.

"The development of NAbs occurs in up to 30 percent of RRMS patients treated with IFN $\beta$  therapy and has been shown to impair the therapeutic effectiveness of IFN $\beta$  therapies," said Dr. Antonio Bertolotto, Centro Riferimento Regionale Sclerosi Multipla (CReSM) and Laboratorio di Neurobiologia Clinica, Ospedale Universitario San Luigi, Orbassano, Italy. "In our MS Center patients with NAbs persistently positive and without IFN $\beta$  biological activity measured by MxA (Myxovirus A) mRNA (Messenger Ribonucleic Acid) and with a Relapse Rate/year of 1 or less

where switched to Copaxone. These data suggest that physicians should discontinue IFN $\beta$  treatment in patients who test positive for NABs and that they should strongly consider switching patients to COPAXONE $\text{\textcircled{R}}$ , as it improves clinical measures of disease activity".

### **About the Study**

The retrospective comparative analysis evaluated changes in relapse rate, proportion of relapse-free patients and time to first relapse between IFN $\beta$  and COPAXONE $\text{\textcircled{R}}$  in NABs-positive patients who were switched to COPAXONE $\text{\textcircled{R}}$ . Patients evaluated in the analysis (n=19) were identified as having persistent NABs positivity (at least 2 months consecutive 3 months apart sera), abolished bioactivity of IFN $\beta$  therapy, as measured by MxA mRNA, low disease activity during IFN $\beta$  treatment (one or fewer relapse in the last year of IFN $\beta$  treatment) and at least 12 months of follow up after COPAXONE $\text{\textcircled{R}}$  introduction.

The mean annualized relapse rate in pre-IFN $\beta$ , IFN $\beta$  NABs-negative, IFN $\beta$  NABs-positive and COPAXONE $\text{\textcircled{R}}$  (glatiramer acetate injection) treatment periods were respectively 0.98, 0.1, 0.32, 0.21 (p<0.001 for pre-IFN $\beta$  treatment period versus each other treatment period; p=NS for other group analyses). The time to first relapse was significantly different among the IFN $\beta$  NABs-negative, IFN $\beta$  NABs-positive and COPAXONE $\text{\textcircled{R}}$  treatment periods, with a significant difference between the IFN $\beta$  NABs-positive and COPAXONE $\text{\textcircled{R}}$  treatment periods (50th percentile: 17.8 versus 37.9 months; 75th percentile: 6.9 versus 12.9 months; p=0.0389).

For additional details on the study design and results, please refer to the poster "Glatiramer acetate reduces disease activity in NABs to IFN $\beta$ -positive patients," by M. Capobianco, A. Sala, S. Malucchi, M. Caldano, A. Di Sapio, F. Sperli, A. Oggero, F. Marnetto, P. Valentino, L. Granieri, F. Gilli, A. Bertolotto.

### **About MS**

Multiple Sclerosis (MS) is the leading cause of neurological disability in young adults. It is estimated that 400,000 people in the United States are affected by this disease, and that over one million people are affected worldwide. MS is a progressive, demyelinating disease of the central nervous system affecting the brain, spinal cord and optic nerves.

Patients with MS may experience physical symptoms and/or cognitive impairments, including weakness, fatigue, ataxia, physical dysfunction, bladder and bowel problems, sensory effects, and visual impairment. MS also has a significant impact on the sufferers' social functioning and overall quality of life.

### **About COPAXONE $\text{\textcircled{R}}$**

Current data suggest COPAXONE $\text{\textcircled{R}}$  (glatiramer acetate injection) is a selective MHC (Major Histocompatibility Complex) class II modulator. COPAXONE $\text{\textcircled{R}}$  is indicated for the reduction of the frequency of relapses in RRMS. The most common side effects of COPAXONE $\text{\textcircled{R}}$  are redness, pain, swelling, itching, or a lump or an indentation at the site of injection, weakness, infection, pain, nausea, joint pain, anxiety, and muscle stiffness.

COPAXONE<sup>®</sup> is now approved in 47 countries worldwide, including the United States, Canada, Mexico, Australia, Israel, and all European countries. In Europe, COPAXONE<sup>®</sup> is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. In North America, COPAXONE<sup>®</sup> is marketed by Teva Neuroscience, Inc.

See additional important information at <http://www.copaxone.com/pi/index.html> or call 1-800-887-8100 for electronic releases. For hardcopy releases, please see enclosed full prescribing information.

## About Teva

Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA), headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the leading generic pharmaceutical company. The company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 75 percent of Teva's sales are in North America and Europe.

*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 Teva's 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: Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which Teva may obtain U.S. market exclusivity for certain of its new generic products and regulatory changes that may prevent Teva from utilizing exclusivity periods, competition from brand-name companies that are under increased pressure to counter generic products, or competitors that seek to delay the introduction of generic products, the impact of consolidation of our distributors and customers, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Allegra<sup>®</sup>, Neurontin<sup>®</sup>, Lotrel<sup>®</sup>, and Famvir<sup>®</sup>, the effects of competition on our innovative products, especially Copaxone<sup>®</sup> sales, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, our ability to achieve expected results through our innovative R&D efforts, Teva's ability to successfully identify, consummate and integrate acquisitions, potential exposure to product liability claims to the extent not covered by insurance, dependence on the effectiveness of our patents and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, environmental risks, fluctuations in currency, exchange and interest rates, and other factors that are discussed in Teva's Annual Report on Form 20-F and its 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.*



**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/ Dan Suesskind

Name: Dan Suesskind  
Title: Chief Financial Officer

Date: October 23, 2007

