

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
October 15, 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**

**LONG-TERM STUDY SHOWS COPAXONE<sup>®</sup> SIGNIFICANTLY SLOWS PROGRESSION OF  
DISABILITY AND REDUCES RELAPSE RATES IN PATIENTS WITH RELAPSING-REMITTING  
MULTIPLE SCLEROSIS**

**Jerusalem, Israel, October 12, 2007** - Data from a 16-year follow-up study of 174 relapsing-remitting multiple sclerosis (RRMS) patients was presented at the 23rd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS). The study demonstrates significant clinical benefits on both disability and relapse rates in patients continuously treated with COPAXONE<sup>®</sup> (glatiramer acetate injection) for an average of 8 years. The majority of patients (84.8 percent) in the ongoing cohort (n=112), who continuously received COPAXONE<sup>®</sup> showed either unchanged or improved disability scores, as measured by Expanded Disability Status Scale (EDSS). In contrast, more than half of patients (56.2 percent) who discontinued treatment after an average of 3.7 years showed accumulated disability. In addition, 76 percent of patients who remained on COPAXONE<sup>®</sup> were still walking unaided after an average of 20 years of disease duration.

In addition to improved EDSS scores, patients who continuously received COPAXONE<sup>®</sup> and were adherent to therapy experienced significantly reduced annualized relapse rates (ARR) compared to baseline (less than one relapse every 4.7 years), with more than half of patients (56.9 percent) remaining relapse-free while on treatment.

"The results of this study demonstrated the sustained positive effects of COPAXONE<sup>®</sup> on slowing disease activity and accumulation of disability in RRMS patients, and further support the drug's excellent long-term safety profile," said Adriana Carrá, M.D., Department of Neurology, Hospital Británico de Buenos Aires. "The results are consistent

with the previously published 10-years long-term data demonstrating the long-term efficacy of COPAXONE® and the drug's beneficial impact on the chronic clinical course of RRMS."

### About the Study

The 16-year study, which represents the longest prospective open-label follow up of RRMS patients in Latin America, evaluated the long-term efficacy and safety of COPAXONE® (glatiramer acetate injection) by examining disability progression and relapse rate among patients who received continuous treatment, and comparing the disease course of these patients to those who withdrew from the study. The observational study, which began in May of 1990, was conducted in eight MS centers in Argentina.

174 treatment naïve RRMS patients were included. Patients were aged between 18-55 years, had experienced two or more relapses in the previous two years and had EDSS disability score below six. Patients with secondary progressive MS and those using immunosuppressant therapies or long-term corticosteroids were excluded. All patients received 20mg dose of COPAXONE® daily by self-injections and had full neurological examinations and EDSS scores determined every six months.

Of the ongoing COPAXONE® treated cohort, 112 patients (64.3 percent) remained in the study for an average of eight years. Of the 62 patients who withdrew from the study (after an average of 3.7 years) 32 (52.5 percent) returned for a single long-term follow up (LTFU) visit.

The clinical features of disability among participants were compared to results from Drs. Weinshenker and Confavreux (Brain 1991, 2006) and an Argentinian natural history cohort of 508 RRMS patients who voluntarily refused treatment or were unable to receive treatment because they had no social security coverage. The data cut-off period for the analysis was in March 2007.

For additional details on the study design and results, please refer to the poster "**The impact of Glatiramer Acetate on progression of disability over a decade of continuous therapy**" A. Carrá, P. Onaha, J. Halfon, V. Sinay R. Bettinelli, M. Burgos, F. Cáceres, J. Correale, E. Cristiano, N. Fernández Liguori, O. Garcea, L. Patrucco, E. Sanpedro, J. Vera, S. Vétere, C. Vrech on behalf of Copaxone Study Group.

### 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®**

Current data suggest COPAXONE® (glatiramer acetate injection) is a selective MHC (Major Histocompatibility Complex) class II modulator. COPAXONE® is indicated for the reduction of the frequency of relapses in RRMS. The most common side effects of COPAXONE® 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® (glatiramer acetate injection) is now approved in 47 countries worldwide, including the United States, Canada, Mexico, Australia, Israel, and all European countries. In Europe, COPAXONE® is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. In North America, COPAXONE® is marketed by Teva Neuroscience, Inc.

Teva Pharmaceutical Industries Ltd., 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 80 percent of Teva's sales are in North America and Europe.

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®reg, Neurontin®reg, Lotrel®reg, and Famvir®reg, the effects of competition on our innovative products, especially Copaxone®reg 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.*

Teva Pharmaceutical Industries Ltd.

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

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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/ Dan Suesskind

Name: Dan Suesskind

Title: Chief Financial Officer

Date: October 12 , 2007

