

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
October 03, 2006

**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 September 2006

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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**STUDY SHOWED SIGNIFICANT AND SUSTAINED EFFICACY OF COPAXONE<sup>®</sup> ALONE  
FOLLOWING SHORT-TERM COMBINATION THERAPY WITH IV STEROIDS IN MULTIPLE  
SCLEROSIS PATIENTS**

*New Data on COPAXONE<sup>®</sup> in Combination Use Presented as Late-Breaking News at ECTRIMS*

**Jerusalem, Israel, September 29, 2006** - A new study showed that continuing treatment with COPAXONE<sup>®</sup> (glatiramer acetate injection) alone, produced pronounced, early and sustained effects on disease activity, following 6 months combination therapy with IV steroids. Multiple sclerosis (MS) patients (n=89) with very active disease, having an average of 5.4 gadolinium (T<sub>1</sub>-W Gd) enhancing lesions at entry as measured by magnetic resonance imaging (MRI) experienced a 65% reduction (p <0.0001) in lesions during treatment with COPAXONE<sup>®</sup> and IV steroids in the first six months of the study. This reduction was sustained for an additional six month period when patients received COPAXONE<sup>®</sup> alone.

These data were presented yesterday as late-breaking news at the 22<sup>nd</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), in Madrid, Spain.

Patients in this study also experienced a reduction in mean annualized relapse rate (ARR) from the pre-study baseline of 1.65±0.74 down to 0.55 and 0.45 during the first and the second study periods, respectively. Results also showed that patients who completed the study experienced a significant decrease in mean converted Kurtzke Expanded Disability Status Scale (EDSS) score as measured after 12 months of treatment as compared to baseline (-0.15, 95 percent CI, -0.13, p=.0323).

"In this patient population with highly active disease as shown by baseline MRI scans, the rapid and significant reduction of brain lesions achieved with COPAXONE<sup>&reg</sup> combined with short-term IV steroid was sustained for an additional six months with COPAXONE<sup>&reg</sup> alone," said Clive Hawkins, D.M., F.R.C.P., Professor of Clinical Neurology, Keele University, Consultant Neurologist to the Regional Neuroscience Centre, Stoke-on-Trent, UK and the lead investigator in this study. "These data may be important for physicians making decisions on how to treat patients with very active disease as characterized by frequent or disabling relapses, or those who do not respond optimally to traditional first-line therapies." added Hawkins.

### **About the Study**

This open-label, one-arm study examined short-term combination therapy of COPAXONE<sup>&reg</sup> and the IV steroid methylprednisolone (IVMP), followed by ongoing treatment with COPAXONE<sup>&reg</sup> alone. Patients with at least two T<sub>1</sub>-weighted gadolinium (T<sub>1</sub>-W Gd) enhancing lesions and an EDSS score of  $\geq$ 4.0 at the time of screening received COPAXONE<sup>&reg</sup> (glatiramer acetate injection) 20mg once daily along with monthly 1g IVMP for six months. After six months, patients continued to receive COPAXONE<sup>&reg</sup> alone for an additional six months.

Disease activity assessed by MRI scans in the first six month period demonstrated a 65 percent reduction (p<0.0001) in the number of T<sub>1</sub>-W Gd-enhancing lesions from baseline. This reduction was sustained in the second six month period and showed no statistical difference from the change achieved in the first six months (ratio 0.75) as shown by a non-inferiority analysis for the change.

Adverse events throughout the 12-month study period were similar to the safety profile of COPAXONE<sup>&reg</sup> alone.

Teva will be issuing a press release regarding additional data presented at ECTRIMS on the efficacy and safety of COPAXONE<sup>&reg</sup> treatment after induction therapy with mitoxantrone, which will be posted at [www.tevapharm.com](http://www.tevapharm.com).

### **About COPAXONE<sup>&reg</sup>**

Current data suggest COPAXONE<sup>®</sup> (glatiramer acetate injection) is a selective MHC class II modulator. COPAXONE<sup>®</sup> is indicated for the reduction of the frequency of relapses in RRMS. The most common side effects of COPAXONE<sup>®</sup> are redness, pain, swelling, itching, or a lump at the site of injection, weakness, infection, pain, nausea, joint pain, anxiety, and muscle stiffness.

COPAXONE<sup>®</sup> is now approved in 44 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.

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. Teva's innovative R&D focuses on developing novel drugs for diseases of the central nervous system.

*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 rapidly integrate Ivax Corporation's operations and achieve expected synergies, Teva's ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic products, the impact of competition from brand-name companies that sell or license their own brand products under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic product, the impact of consolidation of our distributors and customers, regulatory changes that may prevent Teva from exploiting exclusivity periods, potential liability for sales of generic products prior to a final resolution of outstanding litigation, including that relating to the generic versions of Allegra<sup>®</sup>, Neurontin<sup>®</sup>, Oxycontin<sup>®</sup> and Zithromax<sup>®</sup>, the effects of competition on Copaxone<sup>®</sup> sales, including as a result of the reintroduction of Tysabri<sup>®</sup> into the market, 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, Teva's ability to successfully identify, consummate and integrate acquisitions, potential exposure to product liability claims, dependence on patent and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism or major hostilities, environmental risks, fluctuations in currency, exchange and interest rates, operating results 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 publicly or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.*





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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: September 29, 2006



