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 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): _____

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 X

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

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VERY ACTIVE MULTIPLE SCLEROSIS PATIENTS BENEFITED FROM COPAXONE&reg TREATMENT FOLLOWING SHORT-TERM INDUCTION WITH MITOXANTRONE

Induction Regime Reduced MRI-Measured Disease Activity by 89% Which Was Sustained Throughout 15-Month Study

Jerusalem, Israel, September 29, 2006 - A new study showed that very active patients who received COPAXONE&reg (glatiramer acetate injection) therapy alone following short-term induction treatment with mitoxantrone experienced an 89 percent greater reduction ($P<0.0001$) compared to those receiving COPAXONE&reg alone, in Magnetic Resonance Imaging (MRI)-disease activity as measured by Gadolinium (Gd) enhancing lesions of the brain. This initial benefit achieved early on in the study was maintained over the entire 15-month study period. In addition, no adverse events outside of those associated with either treatment when used as monotherapy were observed.

These data were presented today at the 22nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Madrid, Spain.

"These new data represent a promising development in the scientific community`s effort to identify additional effective treatment strategies for those patients who have particularly aggressive forms of RRMS, many of whom do not respond optimally to traditional disease modifying therapies," said Tim Vollmer, M.D., chairman, Division of Neurology, Barrow Neurological Institute at St. Joseph`s Hospital and Medical Center and the primary investigator in this study. "By putting patients on COPAXONE&reg after a brief induction period with mitoxantrone, we were able to significantly reduce MRI-disease activity in the brain of active RRMS patients and to sustain this benefit throughout the study."

About the Study

This randomized, double-blind study looked at the safety, tolerability and efficacy of COPAXONE&reg (glatiramer acetate injection) used after short-term induction therapy with mitoxantrone versus COPAXONE&reg alone. Relapsing-remitting multiple sclerosis (RRMS) patients in this study (n=40) were randomized to receive either COPAXONE&reg for one year following three months of mitoxantrone (M-GA; n=21), or COPAXONE&reg alone for 15 months (GA; n=19). The study included patients aged 18-55, who had a Gd-enhancing lesion at the time of an initial screening MRI scan and an EDSS score of &copy6.5. Patients entering the study were considered very active with a mean number of Gd-enhancing lesions of 3.75. Subsequent brain MRIs were performed at screening and months six, nine, 12 and 15.

Results showing a reduction of Gd-enhancing lesions in the M-GA patient cohort compared with the GA cohort were observed as early as six months into the trial ($p < 0.0001$) and were maintained throughout the duration of the study ($p = 0.0147$). The efficacy demonstrated in the GA cohort increased over the entire 15-months trial; a 46 percent reduction in Gd-enhancing lesions was achieved at nine months and at month 15, patients demonstrated a 67 percent reduction compared to entry.

A relapse was experienced on average eight months prior to baseline in all study participants; after 15 months, the majority of these patients had not experienced a relapse. Patients who received COPAXONE&reg after mitoxantrone showed a trend in experiencing fewer relapses over the study period. Mean relapse rate during the study period was 0.16 in the M-GA group and 0.32 in the GA group, reflecting a 46 percent greater reduction in relapses in M-GA patients than of those that did not receive mitoxantrone ($p=0.31$). There was no difference in time to first relapse between the patient cohorts.

Within study participants, the most frequent adverse events (AEs) associated with the M-GA group were infection, nausea and vomiting, menstruation irregularities and alopecia, and were consistent with known effects of mitoxantrone therapy. Injection site erythema was the most common AE in the GA group.

"Mitoxantrone carries certain risks which limit its use to a maximum recommended lifetime dose. These difficulties make mitoxantrone an option that is generally reserved for only a small group of patients who have a poor disease prognosis or whose disease does not respond to first-line treatment," said Tim Vollmer, M.D., chairman, Division of Neurology, Barrow Neurological Institute at St. Joseph`s Hospital and Medical Center and the primary investigator in this study. "When used after short-term induction with mitoxantrone, COPAXONE&reg minimized exposure to mitoxantrone while maintaining treatment effects ongoing, making it a viable treatment option for a broader proportion of the MS population."

Teva has also issued today a press release regarding additional data presented at ECTRIMS on the efficacy and safety of COPAXONE&reg treatment after short-term combination of COPAXONE&reg and intravenous steroids, which will be posted at www.tevapharm.com.

About COPAXONE&reg

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

COPAXONE&reg is now approved in 44 countries worldwide, including the United States, Canada, Mexico, Australia, Israel, and all European countries. In Europe, COPAXONE&reg is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. In North America, COPAXONE&reg 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&reg, Neurontin&reg, Oxycontin&reg and Zithromax&reg, the effects of competition on Copaxone&reg sales, including as a result of the reintroduction of Tysabri&reg 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.

Teva Pharmaceutical Industries Ltd. Web Site: 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

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