TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
December 03, 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 December 2007

Commission File Number 0-16174

- 1 -

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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For Immediate Release

Early Treatment with COPAXONE&reg Demonstrated Robust Protection against Progression to Clinically Definite Multiple Sclerosis in the PreCISe Study

Efficacy Is Attained and the Study Is Stopped after Interim Analysis and Supports Filing of COPAXONE&reg For Patients with a First Clinical Event Suggestive of MS

Jerusalem, Israel, December 3, 2007- Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced the positive results from a pre-planned interim analysis of the PreCISe trial in patients presenting with a first clinical event and MRI features suggestive of multiple sclerosis (MS). The results showed that treatment with COPAXONE&reg (glatiramer acetate injection) reduced the risk of developing clinically definite MS (CDMS) by 44 percent versus placebo, and prolonged the quartile time to disease conversion to 722 days versus 336 days (+386 days, +115%) in those patients receiving placebo (hazard ratio 0.56, p=0.0005). At the time of the interim analysis, the

proportion of patients who had developed CDMS was reduced from 43 percent in the placebo group to only 25 percent in the COPAXONE&reg group ($p<0.0001$). Based on these results, Teva plans to file a request for marketing authorization of COPAXONE&reg in Europe, the U.S. and Canada for the treatment of patients with a first clinical event suggestive of MS.

Professor Paul O'Connor, Neurology Division Chief at St. Michael's Hospital, Toronto, Canada and the chairman of the study`s independent data monitoring committee (DMC), said, "We are deeply impressed by Teva`s commitment to continue developing COPAXONE&reg for patients presenting with a first clinical event and MRI suggestive of MS. After analyzing the data from the PreCISe study at the interim analysis, the DMC recommended that the placebo arm of the trial be stopped, as COPAXONE&reg successfully met the efficacy endpoint of the study; all placebo patients will now be given the opportunity to receive active treatment with COPAXONE&reg for two years."

This study further demonstrated the beneficial effect of early treatment with COPAXONE&reg on disease activity and burden, also in its early stages, as measured by both short-term clinical and magnetic resonance imaging (MRI) disease outcomes. COPAXONE&reg is the only relapsing-remitting MS (RRMS) treatment with data from a long-term, prospective, ongoing study which demonstrated that in those patients adhering to therapy, 92 percent still walk unassisted after a mean of 10 years of therapy and 18 years of disease duration.

Professor Giancarlo Comi, Department of Neurology, San Raffaele Scientific Institute, Milan, Italy, and principal investigator of the study said, "We are very pleased by the results of this trial. These data on COPAXONE&reg demonstrated the importance of treating patients early on to provide rapid, early control of progression to CDMS, and stand to improve therapy options for the treatment of patients with first clinical event and a high risk to develop MS."

Moshe Manor, Group Vice President - Global Innovative Resources of Teva Pharmaceutical Industries, Ltd., said "The interim results of this study, which showed that early treatment with COPAXONE&reg delayed progression to CDMS, together with the unmatched long-term efficacy, tolerability and favorable safety profile supporting COPAXONE&reg, position it now also as the outstanding treatment option for patients with a first clinical event suggestive of MS and RRMS patients."

About the Study

The multi-national, multi-center, prospective, double-blind, randomized, Phase III PreCISe study was conducted in approximately 100 centers located in the U.S., Europe, Argentina, Israel, Nordic countries, Australia and New Zealand and included a total of 481 patients presenting with a single clinical episode and MRI suggestive of MS. Patients included are those who had a unifocal disease manifestation (i.e., clinical evidence of a single lesion). Patients received either COPAXONE&reg 20mg/day or placebo as a subcutaneous injection and continued treatment for up to 36 months, unless a second attack was experienced and they were diagnosed with clinically definite MS. Patients who converted to CDMS continued the trial on active treatment for additional two years. The primary efficacy outcome was time to CDMS, based on a second clinical attack. The pre-planned interim analysis was performed on data

accumulated from approximately 80 percent of the three-year placebo-controlled study exposure. Over the period up to the interim analysis, the proportion of patients developing CDMS was reduced from 43 percent in the placebo group to only 25 percent in the COPAXONE&reg group (p< 0.0001).

COPAXONE&reg was also very well tolerated in the PreCISe study, with only 13 percent overall dropouts during the up to three-year study period, similar to that observed in RRMS patients treated with COPAXONE&reg. All patients in the study participate in a follow-up study with COPAXONE&reg to prospectively assess the impact of early versus delayed treatment with COPAXONE&reg on the long-term course of the disease for a total observation time of up to five years.

About COPAXONE&reg

Current data suggest COPAXONE&reg is a selective MHC (Major Histocompatability Complex) class II modulator. COPAXONE&reg is indicated for the reduction of the frequency of relapses in RRMS. COPAXONE&reg is very well tolerated and the most common side effects of COPAXONE&reg 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&reg is now approved in 47 countries worldwide, including the United States, all European countries, Canada, Mexico, Australia, and Israel. 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.

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 pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Western Europe. Teva`s innovative R&D focuses on developing novel drugs for diseases of the central nervous system.

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&regNeurontin&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 though 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 : December 3 , 2007