TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
April 06, 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 April 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-_____

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Teva Pharmaceutical Industries Ltd. Web Site: www.tevapharm.com

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FOR IMMEDIATE RELEASE

TEVA ANNOUNCES THAT HIGHER DOSE OF COPAXONE&reg SHOWED INCREASED EFFICACY IN MULTIPLE SCLEROSIS (MS)

Doubling Dose of COPAXONE&reg Further Reduced Relapses and Lesions

Jerusalem, Israel, April 6, 2006 - A new, higher dose of Copaxone&reg (glatiramer acetate injection) shows promising results in the treatment of patients with relapsing-remitting multiple sclerosis (RRMS). A 9-month, randomized, double-blind, parallel-group phase II study of 90 patients comparing a 40 mg dose of Copaxone&reg to the currently approved 20 mg dose showed a 38% greater reduction in mean cumulative number of gadolinium (Gd)-enhancing lesions as measured by magnetic resonance images (MRI) of the brain in patients taking the higher dose compared with those taking the 20 mg dose. In addition, patients taking Copaxone&reg 40 mg experienced a reduced mean on-trial relapse rate of 77% when compared to annual relapse rate prior to entry, as compared to 62% with Copaxone&reg 20 mg.

These study results were announced as a Late Breaking Science platform presentation at this year`s 58th Annual Meeting of the American Academy of Neurology (AAN) in San Diego, CA, April 1-8, 2006.

"These results suggest that a 40 mg dose of Copaxone&reg may provide even better control of disease activity within the central nervous system than the currently approved 20 mg dose," said Jeffrey A. Cohen, Director of the Experimental Therapeutics Program at the Cleveland Clinic's Mellen Center for MS Treatment and Research and Coordinating Principal Investigator of the study. "The higher dose showed promise in terms of providing additional treatment benefits to RRMS patients, paving the way for additional research on this increased therapeutic dose of Copaxone&reg."

Data from this study demonstrated that Copaxone&reg 40 mg was well-tolerated with a safety profile similar to the currently available 20 mg dose. The efficacy and safety of the approved 20 mg dose of Copaxone&reg have been well established by three pivotal trials and over a decade of experience and clinical research.

"Following these results, we are planning to conduct a large-scale Phase III study designed to confirm the higher efficacy of Copaxone&reg with the increased dose. The Phase III study is expected to be launched in the second half of 2006," said Israel Makov, President and Chief Executive Officer of Teva Pharmaceutical Industries Ltd. "This study is part of our strong clinical development program in MS - a program designed to help MS patients and improve their quality of life."

Study Design and Results

The study was a randomized, double-blind, parallel-group study conducted at 18 centers in the U.S. in 90 patients with RRMS. The study evaluated the effect of 40 mg of Copaxone&reg versus 20 mg of Copaxone&reg on disease activity as measured by MRI and clinical relapses, as well as the safety and tolerability of the 40 mg dose over a period of 9 months. Patients that qualified for this study had clinically-definite MS, had experienced a relapse in the previous year, had at least one Gd-enhancing lesion at screening visit, and had a Kurtzke Expanded Disability Status Scale (EDSS) score of 0-5. Patients were randomized in equal numbers to receive either 40 mg or 20 mg of Copaxone&reg. All patients underwent an MRI at baseline, and then at months 3, 7, 8 and 9. Neurological examinations were performed at screening, baseline, and again at months 3, 6 and 9, and suspected on-trial relapses were confirmed at an unscheduled visit within 7 days. The difference between the two treatment arms was assessed using a Poisson regression model accounting for potential differences in study-site and in baseline gadolinium (Gd)-enhancing lesion counts.

Copaxone&reg 40 mg showed a 38% greater reduction of inflammatory disease activity as measured by mean cumulative number of Gd-enhancing T1 MRI lesions versus Copaxone&reg 20 mg (p=0.0898). The benefit of the 40 mg dose was observed in as soon as 3 months (p=0.005) through MRI measurement. When compared to baseline numbers, the risk of having MRI activity (Gd-enhancement) in the 40 mg group at months 7, 8 and 9 was reduced by 75% (p<0.0001), compared to 65% in patients receiving the 20 mg dose (p<0.0001).

Relapse rates were also lower in patients who received the 40 mg dose of Copaxone&reg, when compared to those who received 20 mg dose (0.34 versus 0.57, respectively). Patients on 40 mg dose of Copaxone&reg experienced a reduced on-trial mean relapse rate of 77% when compared to the annual relapse rate prior to entry, versus patients who received the 20 mg dose (62% reduction). The time to the first relapse was significantly delayed from 80 days in the 20 mg group to 213 days in the 40 mg group (p = 0.0367).

About Multiple Sclerosis

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 two 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&reg

Copaxone&reg (glatiramer acetate injection) is indicated for the reduction of the frequency of relapses in patients with RRMS.

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.

Current data suggest Copaxone&reg is a selective MHC class II modulator.

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.

Teva Pharmaceuticals USA and Teva Neuroscience, Inc. are subsidiaries of Teva Pharmaceutical Industries Ltd. Teva Neuroscience, Inc. markets Copaxone&reg. Copaxone&reg is a registered trademark of Teva Pharmaceutical Industries Ltd.

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.

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. Close to 90% 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 competitive generic products, the impact of competition from brand-name companies that sell or license their own generic products under generic trade dress and at generic prices (so called "authorized generics") or seek to delay the introduction of generic products ,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 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 expected 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 Association and other regulatory authority approvals, the regulatory environment and changes in the health policies and structure of various countries, Teva`s ability to successfully identify, consummate and integrate acquisitions, 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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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: April 6, 2006

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