TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
May 02, 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 May 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 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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LAQUINIMOD, A NOVEL ORAL COMPOUND, SHOWED SIGNIFICANT REDUCTION IN DISEASE ACTIVITY IN PATIENTS WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS (RRMS)

Jerusalem, Israel and Lund, Sweden, May 1, 2007 - Teva Pharmaceutical Industries Ltd. and Active Biotech AB today announced that data from a 36-week, randomized, double-blind, placebo-controlled Phase IIb study demonstrated that an oral 0.6 mg dose of laquinimod given daily significantly reduced magnetic resonance imaging (MRI) disease activity by 38 percent in RRMS patients and was well tolerated. In addition, there was a favorable trend towards reducing annual relapse rates, the number of relapse-free patients and time to first relapse compared with placebo. Treatment with a 0.3 mg dose showed no statistical significant difference compared with placebo.

These data were presented at the 59th Annual Meeting of the American Academy of Neurology (AAN) in Boston, MA, April 28 - May 5, 2007.

"Current RRMS options are effective for the treatment of the disease, but an oral therapy such as laquinimod would represent a milestone for patients as it would provide them with a completely unique, non-invasive method of drug delivery," said Giancarlo Comi, M.D., Director of Department of Neurology and Institute of Experimental Neurology, Universita Vita-Salute, San Raffaele, Milan, Italy. "Preliminary studies have already demonstrated the positive effect of laquinimod versus placebo, but these new data confirmed that a higher dose was even more effective and remained well tolerated."

The 36-week study evaluated the effect of oral daily 0.3 and 0.6 mg doses of laquinimod on MRI-monitored disease activity in patients with RRMS. The majority of the patients who participated in the study continued treatment with laquinimod in an ongoing, blinded 9 month extension study. This extension study is followed by an open label study where patients will receive 0.6 mg laquinimod for an additional 24 months.

"The results of this study, which once again demonstrate the efficacy and tolerability of once-daily oral laquinimod, are very exciting for the MS community-both patients and researchers," said Shlomo Yanai, President and CEO of Teva Pharmaceutical Industries Ltd. "Teva will soon initiate Phase III studies to confirm oral laquinimod`s therapeutic benefits, and we expect to begin enrollment of the trial later this year."

About the Study

Study participants were required to have experienced one or more relapses in the year prior to entry and at least one Gd-enhancing lesion at screening. The patients (n=306) in the study were randomized to receive placebo (n=102), 0.3 mg dose of laquinimod (n=98) or 0.6 mg dose of laquinimod (n=106). At entry, active treatment and placebo groups were comparable for demographic, clinical and MRI characteristics.

Patients were assessed clinically and by MRI scan at week -4, baseline, and monthly from weeks 12 to 36. The primary outcome of the study was the cumulative number of Gd-enhancing lesions at weeks 24, 28, 32 and 36. Secondary outcomes of the study included additional MRI metrics and confirmed relapse rate.

The laquinimod 0.6 mg dose showed a reduction compared with placebo in the cumulative number of enhancing lesions per scan in the last four scans (mean SD= 2.6 5.3 vs. 4.2 9.2, p = 0.0048); treatment with the 0.3 mg dose showed no significant difference. Significant differences in favor of the 0.6 mg dose were found for most examined secondary and exploratory MRI-based outcome measures. Trends favored the group receiving the 0.6 mg dose on measures of annual relapse rate (0.52 +/- 0.92 vs. placebo 0.77 +/- 1.25; p = 0.21), relapse-free subjects (70.8 percent vs. 62.7 percent; p = 0.33) and time to first relapse (p = 0.14).

Treatment with both 0.3 and 0.6 mg doses of laquinimod were well tolerated with only some transient and dose-dependent increases in liver enzymes.

About laquinimod

Laquinimod is a novel once-daily, orally administered immunomodulatory compound developed as a disease modifying treatment for multiple sclerosis (MS). Active Biotech developed laquinimod and licensed it to Teva Pharmaceutical Industries, Ltd. in June 2004. A previous 24-week Phase IIa trial conducted by Active Biotech demonstrated that oral 0.3 mg laquinimod given daily was well tolerated and reduced the formation of active lesions in RRMS. To date, 460 MS patients have received laquinimod in various clinical trials.

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 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. Close to 90 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.

About Active Biotech

Active Biotech AB (ACTI.ST) is a biotechnology company focusing on research and development of pharmaceuticals. Active Biotech has a strong R&D portfolio with pipeline products focused on autoimmune/inflammatory diseases and cancer. Most advanced projects are laquinimod, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, as well as ANYARA for use in cancer targeted therapy, the primary indication being renal cancer. Further key projects in clinical development comprise the three orally administered compounds TASQ for prostate cancer, 57-57 for SLE and RhuDex&reg for RA. In addition, the preclinical development of the I-3D project is being conducted in cooperation with Chelsea Therapeutics International Ltd.

***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 and Neurontin&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.*

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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: May 1, 2007

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