TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
November 07, 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 November 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-_____

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

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For Immediate Release

INITIATION OF ENROLLMENT IN PIVOTAL PHASE III CLINICAL STUDY OF ORAL LAQUINIMOD FOR RELAPSING-REMITTING MULTIPLE SCLEROSIS

Jerusalem, Israel and Lund, Sweden, November 7, 2007 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech AB (OMX NORDIC: ACTI) announced today the initiation of enrollment in the Allegro trial (assessment of oral laquinimod in preventing progression of multiple sclerosis). Allegro is a global pivotal, 24/30-month, double-blind, Phase III study designed to evaluate the efficacy, safety and tolerability of the oral investigational compound laquinimod versus placebo in the treatment of relapsing-remitting multiple sclerosis (RRMS). The Allegro trial aims to enroll approximately 1,000 patients with RRMS.

"Currently there are several RRMS treatments available; however, they are all administered via injection or infusion. An orally administered therapy brings us one step closer to offering patients and physicians a highly effective, new,

convenient and less invasive method of drug delivery," said Doug Jeffery, M.D., Ph.D., Associate Professor, Wake Forest University Baptist Medical Center. "Previous Phase II studies have demonstrated positive results for laquinimod, and we hope that results from this pivotal Phase III trial will further reinforce these findings."

Recently, Teva concluded a 36-week extension of the 36-week Phase IIb core trial, which demonstrated that laquinimod 0.6 mg met its primary endpoint. The data from this extension trial further confirmed and strengthened the results from the initial 36-week Phase IIb trial. The majority of the patients that have participated in the trial are now receiving treatment with laquinimod in a continued open-label extension trial.

"The initiation of Phase III clinical trial is a critical milestone for Teva in our commitment to the MS community," said Moshe Manor, Group Vice President - Global Innovative Resources, of Teva Pharmaceutical Industries Ltd."We are excited about the development of Laquinimod, which together with Copaxone, will broaden our MS platform and position Teva as a leading company in the MS field".

Additional new data, presented at the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) on October 13, 2007 in Prague, demonstrated that laquinimod reduced inflammation, demyelination and axonal damage in an animal model experimental autoimmune encephalomyelitis (EAE), indicating that the compound may have both anti-inflammatory and neuroprotective properties.

Based on encouraging results from various animal models, laquinimod is now being investigated for other autoimmune diseases.

"We are very pleased to see how Teva has successfully advanced the laquinimod clinical trial program in order to bring a novel, first-in-class product to the market for the treatment of MS," said Sven Andréasson, President and CEO of Active Biotech AB.

The efficacy, safety, and tolerability of laquinimod will also be studied in an additional Phase III pivotal trial in RRMS (BRAVO), which is expected to begin enrollment in the first quarter of 2008. This trial is a multinational, multi-center, randomized, parallel-group, placebo-controlled study which will compare the effects of laquinimod to those of placebo, and provide risk-benefit data comparing once-daily orally administered laquinimod to a product presently used for treatment of RRMS (an active comparator). This study plans to enroll approximately 1,200 participants who will be followed for 24 months.

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 the 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. Demyelination is the destructive breakdown of the fatty tissue that protects nerve endings.

About Allegro

Allegro is a multinational, multi-center, randomized, double-blind, parallel-group, placebo-controlled study, currently enrolling approximately 1,000 patients with RRMS. The globally conducted study will include centers in the United States as well as centers throughout Canada, Europe, and Israel. To learn more about Allegro, visit www.TevaClinicalTrials.com or call 1-866-550-0614.

About Laquinimod

Laquinimod is a novel once-daily, orally administered immunomodulatory compound that is being developed as a disease-modifying treatment for RRMS. Active Biotech developed laquinimod and licensed it to Teva Pharmaceutical Industries, Ltd. in June 2004. A recent Phase IIb study in 306 patients was presented at the 2007 Annual Meeting of the American Academy of Neurology (AAN). The data demonstrated that an oral 0.6 mg dose of laquinimod, administered daily, significantly reduced magnetic resonance imaging (MRI) disease activity by 40 percent versus placebo (p=0.0048) in RRMS patients, and was well tolerated. Looking into the median data of the primary end point laquinimod 0.6mg reduces disease activity (MRI) by 55% compared to placebo. Laquinimod showed consistent and robust effect (statistical significant) on all secondary MRI end points. In addition, the study showed a favorable trend toward reducing annual relapse rates and the number of relapse-free patients compared with placebo. Treatment with both 0.3 and 0.6 mg doses were well tolerated with only some transient and dose-dependent increases in liver enzymes reported. To date 460 MS patients have received laquinimod in various clinical trials.

Active Biotech AB

Active Biotech AB (OMX NORDIC: ACTI) 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, primarily 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 autoimmunity project I-3D is in preclinical development. www.activebiotech.com

About Teva

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 pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Western Europe.

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, Neurontin&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: November 7 , 2007

__3__