TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
February 17, 2009

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 February 2009

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-_____

www.tevapharm.com www.activebiotech.com

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For immediate release

ORAL LAQUINIMOD FOR MULTIPLE SCLEROSIS GRANTED FAST TRACK STATUS BY FDA

Jerusalem, Israel and Lund, Sweden, February 12, 2009 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech (NASDAQ OMX NORDIC: ACTI) today announced that oral laquinimod, an investigational treatment for relapsing-remitting multiple sclerosis (RRMS), has received a Fast Track designation from the U.S. Food and Drug Administration (FDA). Teva completed enrollment for the first of its two Phase III clinical trials for laquinimod (ALLEGRO) in November 2008 and is currently enrolling RRMS patients globally for the second Phase III study (BRAVO).

Drugs designated for Fast Track are intended for the treatment of a serious or life-threatening condition and have demonstrated the potential to address unmet medical needs. Fast Track designation can potentially facilitate development and expedite the review process. This may allow the drug to enter the market as soon as late 2011.

"As global leaders in the treatment of multiple sclerosis, Teva is committed to bringing additional safe, effective and convenient therapies to MS patients," said Moshe Manor, Vice President, Global Innovative Resources Group at Teva. "We are pleased that the FDA has awarded laquinimod with a Fast Track designation, and are hopeful it will be part of

our growing portfolio of innovative therapies."

"We're encouraged by the reports we've seen from the Phase II clinical trial of laquinimod, and if this agent continues to prove safe and effective, it would be a welcome new treatment option available to people with multiple sclerosis," said Dr. John Richert, Executive Vice President, Research and Clinical Programs, National MS Society.

Laquinimod is a novel, once-daily, orally administered immunomodulatory compound being studied as a disease-modifying treatment for RRMS. For more information on the ongoing laquinimod Phase III clinical program, please visit www.TevaClinicalTrials.com or call 1-800-840-5601.

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. Results from a Phase IIb study in 306 patients were published in June 2008 in *The Lancet* and reported that an oral 0.6 mg dose of laquinimod, administered daily, significantly reduced MRI disease activity by a median of 60 percent (51 percent mean reduction) versus placebo in RRMS patients. In addition, the study showed a favorable trend toward reducing annual relapse rates and in the number of relapse-free patients compared with placebo. Treatment was well tolerated, with some transient and dose-dependent increases in liver enzymes reported, without clinically-evident liver damage.

In addition to the efficacy that laquinimod has shown in Phase II RRMS clinical trials, laquinimod has demonstrated potent therapeutic efficacy in preclinical models of other autoimmune diseases such as Crohn`s disease, rheumatoid arthritis, insulin-dependent diabetes mellitus, Guillain Barré Syndrome, and Lupus. The broad profile of efficacy in animal models of inflammatory diseases suggests that laquinimod affects a pivotal pathway of inflammation and autoimmunity. Teva has also initiated a clinical study to evaluate laquinimod for Crohn`s disease and expects to initiate the clinical development of laquinimod for Lupus Nephritis in the near future.

About the Phase III Program

Allegro (assessment of oral laquinimod in preventing progression of MS), a pivotal, global, 24/30-month, randomized, double-blind, Phase III study designed to evaluate the efficacy, safety and tolerability of laquinimod versus placebo in the treatment of RRMS, completed recruitment of more than 1,000 patient at 152 sites throughout North America, Europe and Asia in November 2008.

Bravo (benefit-risk assessment of Avonex&reg and laquinimod), a pivotal, global, 24 month, randomized, double-blind, parallel-group, placebo-controlled Phase III study designed to compare the safety and efficacy of laquinimod with placebo and to provide risk-benefit data for laquinimod versus a currently available injectable treatment, is currently enrolling patients at centers throughout the United States, as well as Canada, Europe and Israel. The enrollment goal is

approximately 1,200 patients with RRMS. To learn more about Teva's ongoing clinical trials, please visit www.TevaClinicalTrials.com or call 1-800-840-5601.

About Multiple Sclerosis

Multiple Sclerosis (MS) is the leading cause of neurological disability in young adults. It is estimated that more than 400,000 people in the United States are affected by the disease and that two million people may be 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 Teva

Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA), headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the world's leading generic pharmaceutical company. The Company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients. Over 80 percent of Teva's sales are in North America and Europe.

About Active Biotech

Active Biotech AB (NASDAQ OMX NORDIC: ACTI), headquartered in Sweden, is a biotechnology company with R&D focus on autoimmune/inflammatory diseases and cancer. Projects in pivotal phase 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(TM) for RA. Please visit www.activebiotech.com for more information.

Teva's 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 our 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: our ability to successfully develop and commercialize additional pharmaceutical products, the introduction of competing generic equivalents, the extent to which we may obtain U.S. market exclusivity for certain of our new generic products and regulatory changes that may prevent us 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 Neurontin&reg, Lotrel&reg and Protonix&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, our ability to successfully identify, consummate and integrate acquisitions, including the integration of Barr Pharmaceuticals Inc., 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 this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

Active Biotech`s Safe Harbor Statement in Accordance with the Swedish Securities Market Act:

This press release contains certain forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause the actual results, performance or achievements of the company, or industry results, to differ materially from any future results, performance or achievement implied by the forward-looking statements. The company does not undertake any obligation to update or publicly release any revisions to forward-looking statements to reflect events, circumstances or changes in expectations after the date of this press release.

Active Biotech is obligated to publish the information contained in this press release in accordance with the Swedish Securities Market Act. This information was submitted for publication on February 12, 2009 at 9:00a.m. ET.

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/ Eyal Desheh

Name: Eyal Desheh
Title: Chief Financial Officer

Date: February 12, 2009