

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
June 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 June 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

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

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b):  
82- \_\_\_\_\_



Active Biotech AB

[www.activebiotech.com](http://www.activebiotech.com)

[www.tevapharm.com](http://www.tevapharm.com)

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**Teva and active biotech to initiate pivotal phase III trial Program of ORAL laquinimod for relapsing multiple sclerosis**

**Jerusalem, Israel and Lund, Sweden, June 7, 2007** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech AB (OMX NORDIC: ACTI) today announced that the companies are initiating a clinical Phase III program for laquinimod, a novel once-daily, orally administered immunomodulatory compound for the treatment of relapsing multiple sclerosis (RMS). The studies will now begin following the successful conclusion of a second phase II study and the outcome of discussions with the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

The companies are to commence two global Phase III trials of laquinimod during this year. The Phase III trials will take place in centers in the United States, Europe, and other locations worldwide, to further confirm the results of the Phase II trials.

"We are extremely excited about initiating the Phase III clinical program for oral laquinimod, as we believe laquinimod is a potential new and convenient treatment option for MS patients," said Shlomo Yanai, President and CEO of Teva Pharmaceutical Industries Ltd. "The accelerated development of oral laquinimod is part of our commitment to MS patients to develop additional improved therapies that combine superior efficacy and excellent safety."

"Laquinimod has the potential to be a novel, orally-administered disease modifying treatment for people suffering from multiple sclerosis," said Sven Andréasson, President and CEO of Active Biotech. "Laquinimod would represent a milestone for patients as it would provide them with an efficacious and safe treatment, as well as a new drug delivery option that is suitable for long-term treatment."

### **About Phase II Laquinimod Trials**

Results from a 36-week, randomized, double-blind, placebo-controlled Phase IIb trial evaluating the effect of oral daily 0.3 and 0.6 mg doses of laquinimod on magnetic resonance imaging (MRI) -monitored disease activity in patients with RRMS were recently presented at the American Academy of Neurology (AAN) Annual Meeting in May, 2007. Data from the trial demonstrated that an oral 0.6 mg dose of laquinimod given daily significantly reduced MRI disease activity by 40 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 both 0.3 and 0.6 mg doses of laquinimod were well tolerated with only some transient and dose-dependent increases in liver enzymes.

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.

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### **About Laquinimod**

Laquinimod is a novel once-daily, orally administered immunomodulatory compound that is being 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. 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. Over 76 percent of Teva's sales are in North America and Europe. Teva`s innovative R&D focuses on developing novel drugs, primarily for diseases of the central nervous system.

## About Active Biotech

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, 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<sup>®</sup> for RA. In addition, the preclinical development of the I-3D project is being conducted in cooperation with Chelsea Therapeutics International Ltd.

***Teva Safe Harbor Statement under the U. S. Private Securities Litigation Reform Act of 1995: 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<sup>®</sup> and Neurontin<sup>®</sup>, the effects of competition on our innovative products, especially Copaxone<sup>®</sup> 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 through 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](http://www.tevapharm.com)

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**SIGNATURES**

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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: June 7, 2007

