

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
April 28, 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 April 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

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-



Contact: **Elana Holzman** Teva Pharmaceutical Industries Ltd. 972 (3) 926-7554  
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**For Immediate Release**

**NEW DATA ILLUSTRATE NOVEL Mechanism of Action of LAQUINIMOD, an ORAL COMPOUND FOR the treatment of MULTIPLE SCLEROSIS**

*- Researchers Demonstrate Immunomodulatory Effects of Laquinimod on Disease Activity -*

**Jerusalem, Israel, Lund, Sweden and Seattle, Washington, April 28, 2009** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech (NASDAQ OMX NORDIC: ACTI) today announced results from several new clinical and preclinical studies providing further insight on the immunomodulatory mechanism of action (MOA) of laquinimod, a novel oral once-daily compound being developed for the treatment of relapsing-remitting multiple sclerosis (RRMS). Four sets of data being presented at the 61<sup>st</sup> Annual Meeting of the American Academy of Neurology (AAN) in Seattle stand to increase the understanding of how laquinimod may reduce multiple sclerosis (MS) activity and affect mechanisms related to disease pathology.

While research looking at the mechanism by which the compound exerts its clinical effect is ongoing, currently available data indicate that laquinimod impacts RRMS by modulating key processes of the immune system, and suggest an immunomodulating effect within the central nervous system (CNS).

"As we continue to study how laquinimod impacts multiple sclerosis, we remain encouraged by the potential of this oral candidate," explains Scott Zamvil, M.D., Ph.D., Associate Professor, Department of Neurology, University of California, San Francisco. "Laquinimod, with a balanced safety and efficacy profile, may address a currently unmet medical need for patients seeking effective oral therapy for MS that is well tolerated and safe."

Laquinimod recently received Fast Track designation from the U.S. Food and Drug Administration (FDA), which may allow the drug to enter the market as soon as late 2011. Teva completed enrollment for the first of its two Phase III clinical trials for laquinimod (ALLEGRO) in November 2008, and the second global Phase III study (BRAVO) is on schedule to complete patient enrollment in the first half of 2009.

## ABOUT THE STUDIES

The studies evaluating the MOA of laquinimod being presented at AAN include:

### **Effect of laquinimod on the dendritic cell compartment (Poster session I, April 28 from 7:00 AM - 10:00 AM, Room 6E)**

*Tal Birnberg, Steffen Jung, Rehovot, Israel*

o Results from this additional murine study demonstrate that the effect of laquinimod on autoimmune deviation may also be due, in part, to its impact on the dendritic cell compartment, which is critical for the initiation and perpetuation of T cell-driven autoimmune disorders.

### **Down regulation of antigen presentation and inflammatory pathways by laquinimod in cultured peripheral blood mononuclear cells of untreated multiple sclerosis patients and healthy subjects (Poster session I, April 28 from 7:00 AM - 10:00 AM, Room 6E)**

*Rotem Or-Bach, Polina Sonis, Michael Gurevich, Anat Achiron, Ramat-Gan, Israel*

o Data demonstrate laquinimod is intricately involved in the inflammatory response. Specifically, the early molecular events induced by laquinimod in RRMS patients were shown to potentially be the down regulation of MHC-class II gene transcription factors, the suppression of pro-inflammatory and cytokine related genes and the activation of an anti-inflammatory gene.

### **Laquinimod inhibits MOG-induced experimental autoimmune encephalomyelitis (EAE) in CD4+CD25+ regulatory T-cell depleted mice (Poster session VIII, April 30 from 11:30 AM - 2:30 PM, Room 6E)**

*Nora Tarcic, Emanuel Raymond, Joel Kaye, Netanya, Israel*

o Results show laquinimod is effective in inhibiting disease severity with or without the presence of CD4+CD25+ cells, indicating the compound does not require this specific regulatory pathway. These findings further define its immunomodulatory effect.

### **The effect of laquinimod on lymphocyte VLA-4 properties under shear flow conditions (Scientific session, April 30 from 1:30 PM - 3:30 PM, Room 605/610)**

*Liat Hayardeny, Sara Feigelson, Valentin Grabovsky, Joel Kaye, Rotem Keshet, Guy Cinamon, Ronen Alon, Netanya, Israel, Rehovot, Israel*

- o New data from this evaluation of a murine model suggest laquinimod selectively inhibits the chemokine-induced activation of T cell VLA-4 binding to VCAM-1, an endothelial cell adhesion molecule involved in T cell migration into the CNS. These data suggest a novel MOA of laquinimod.

## **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 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 Phase IIb study in 306 patients was recently published in *The Lancet* and demonstrated that an oral 0.6 mg dose of laquinimod, administered daily, significantly reduced MRI disease activity by a median of 60 percent versus placebo in RRMS patients. In addition, the study showed a favorable trend toward reducing annual relapse rates and the number of relapse-free patients compared with placebo. Treatment was well tolerated, with only some transient and dose-dependent increases in liver enzymes reported. Over 1000 MS patients have received laquinimod in various clinical trials.

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 rheumatoid arthritis, insulin-dependent diabetes mellitus, Guillain Barré Syndrome, lupus and Inflammatory Bowel Disease. The broad profile of efficacy in animal models of inflammatory diseases suggests that laquinimod affects a pivotal pathway of inflammation and autoimmunity. Laquinimod is currently in Phase II development for Crohn's disease and Teva expects to initiate the clinical development of the compound for Lupus Nephritis in the near future.

## **ABOUT ACTIVE BIOTECH**

Active Biotech AB (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™ for RA. Please visit [www.activebiotech.com](http://www.activebiotech.com) for more information.

## **ABOUT TEVA**



Teva Pharmaceutical Industries Ltd., 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, as well as animal health pharmaceutical products. Over 80 percent of Teva's sales are in North America and Europe.

**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, 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® and Lotrel® and Protonix®, the current economic conditions, 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 effects of competition on our innovative products, especially Copaxone® sales, dependence on the effectiveness of our patents and other protections for innovative products, the impact of consolidation of our distributors and customers, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, our ability to achieve expected results through our innovative R&D efforts, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the uncertainty surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, the regulatory environment and changes in the health policies and structures of various countries, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, our ability to successfully identify, consummate and integrate acquisitions, including the integration of Barr Pharmaceuticals, Inc., the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, our ability to enter into patent litigation settlements and the intensified scrutiny by the U.S. government, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, environmental risks, 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.*

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Teva Pharmaceutical Industries Ltd.

Web Site: [www.tevapharm.com](http://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/ Eyal Desheh

Name: Eyal Desheh  
Title: Chief Financial Officer

Date: April 28, 2009

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