

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
June 29, 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 June 29, 2009

Commission File Number 0-16174



1

**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):  
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**For Immediate Release**

### **Teva Completes Enrollment in Second Oral Laquinimod Phase III MS Clinical Trial**

**Jerusalem, Israel and Lund, Sweden, June 26, 2009** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech (NASDAQ OMX NORDIC: ACTI) today announced completion of patient enrollment for the second pivotal Phase III clinical trial, BRAVO, evaluating the novel, oral once-daily immunomodulating compound, laquinimod, for the treatment of relapsing-remitting multiple sclerosis (RRMS). BRAVO is a global clinical trial designed to evaluate the efficacy, safety and tolerability of laquinimod versus placebo, and to provide risk-benefit data for laquinimod versus a currently available injectable treatment, Avonex<sup>®</sup>.

The BRAVO study completed patient enrollment in June, recruiting more than 1,200 patients at 156 sites in the United States, Europe, Israel and South Africa.

"Teva and Active Biotech are encouraged by the potential of laquinimod to address patients' unmet need for an oral immunomodulating MS therapy that provides efficacy while maintaining safety" said Moshe Manor, Teva's Group Vice President, Global Branded Products. "We look forward to continuing our clinical Phase III program of laquinimod, and hope it will offer enhanced quality of health for RRMS patients".

ALLEGRO, the first global Phase III trial of laquinimod, completed enrollment in November 2008, after recruiting more than 1,000 patients at 152 sites in North America, Europe and Asia. The trial is currently ongoing.

In February 2009, laquinimod received Fast Track designation from the U.S. Food and Drug Administration (FDA).

**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 over 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 published in *The Lancet* (June 2008) and demonstrated 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 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.

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 the Phase III Program**

ALLEGRO (assessment of oral laquinimod in preventing progression of MS) is a pivotal, global, 24/30-month, double-blind, Phase III study designed to evaluate the efficacy, safety and tolerability of laquinimod versus placebo in the treatment of RRMS.

BRAVO (benefit-risk assessment of Avonex<sup>®</sup> and laquinimod) is a pivotal, multinational, multi-center, randomized, double-blind, parallel-group, placebo-controlled 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.

### **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, as

well as animal health pharmaceutical products. 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™ for RA. Please visit [www.activebiotech.com](http://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, 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<sup>®</sup>, Lotrel<sup>®</sup> and Protonix<sup>®</sup>, 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<sup>®</sup> 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 :June 26, 2009