

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
July 16, 2008

**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 July 2008

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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**For Immediate Release**

**TEVA ENROLLS PATIENTS FOR A SECOND LARGE GLOBAL PHASE III TRIAL OF ORAL  
LAQUINIMOD**

*The BRAVO trial, together with the ongoing ALLEGRO trial will investigate oral laquinimod in more than 2,000  
RRMS patients worldwide*

**Jerusalem, Israel and Lund, Sweden, July 16, 2008** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech AB (OMX NORDIC: ACTI) announced today that patients are being enrolled for the BRAVO Phase III pivotal trial. BRAVO is a global, 24-month, double-blind study designed to evaluate the efficacy, safety and

tolerability of the oral compound laquinimod versus placebo, and to provide risk-benefit data for laquinimod versus a currently available injectable treatment, Avonex<sup>®</sup>. The BRAVO trial, which was initiated in April this year, aims to enroll approximately 1,200 patients with relapsing-remitting multiple sclerosis (RRMS). A second global Phase III trial of laquinimod including 1,000 patients, ALLEGRO, is also ongoing and recruiting patients globally.

"All currently approved multiple sclerosis (MS) treatments are administered via injection or infusion. The ability to provide a safe and effective oral treatment option would be a significant advancement for the treatment of MS," said Dr. Timothy Vollmer, Medical Director, Rocky Mountain MS Center, Denver, Colorado, and principal investigator of the BRAVO study. "Additionally, the mode of action for laquinimod is unlike any other MS compound, existing or experimental. We are hopeful that this research will expand our abilities to combat the disease through novel targeting."

Data recently published in *The Lancet*<sup>\*</sup> demonstrated that oral dose of laquinimod significantly reduced the median magnetic resonance imaging (MRI) disease activity by 60 percent, compared to placebo and was well tolerated in RRMS patients. The majority of patients from the study are still receiving treatment with laquinimod in an open-label extension trial.

The safety profiles of oral therapies are of increasing interest to the MS community; We are hopeful that laquinimod will be both efficacious and safe thus providing patients with an optimal risk-benefit profile," said Dr. Per Soelberg Sorensen, Danish Multiple Sclerosis Research Center, Department of Neurology, Copenhagen University Hospital, and principal investigator of the BRAVO study.

### **About Multiple Sclerosis**

Multiple Sclerosis (MS) is the leading cause of neurological disability in young adults. It is estimated that over four hundred thousand 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 BRAVO**

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, Avonex<sup>®</sup>. The enrollment goal is approximately 1,200 patients with RRMS. The globally conducted study will include centers in the United States, Europe, and Israel. To learn more about BRAVO visit [www.TevaClinicalTrials.com](http://www.TevaClinicalTrials.com) or call 1-800-840-5601.

### **About ALLEGRO**

ALLEGRO 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 relapsing-remitting multiple sclerosis (RRMS). The Allegro trial aims to enroll 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](http://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 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. Laquinimod also showed consistent and robust effect on all secondary MRI endpoints. 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 460 MS patients have received laquinimod in various Phase I-II 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. Teva expects to initiate the clinical development of laquinimod for Crohn's disease and Lupus Nephritis in the near future.

### **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. Please visit [www.tevapharm.com](http://www.tevapharm.com) for more information on Teva Pharmaceutical Industries Ltd.

### **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&reg 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 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 accurately predict future market conditions, 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® , Neurontin® , Lotrel® , Famvir® and Protonix® , 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, the effects of competition on our innovative products, especially Copaxone® 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 (including the pending acquisition of Bentley 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 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.*

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: July 16, 2008

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\* Lancet 2008;371:2085-92