

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
November 19, 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 November 2008

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

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**For Immediate Release****Teva Completes Enrollment in Laquinimod Phase III Clinical Trial**

- *Recruitment Still Ongoing For Second, Pivotal Phase III Study, Bravo* -

**Jerusalem, Israel and Lund, Sweden, November 18, 2008** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech (NASDAQ OMX NORDIC: ACTI) today announced completion of patient enrollment for the Phase III clinical trial, Allegro, in relapsing-remitting multiple sclerosis (RRMS). The pivotal Allegro study is designed to evaluate the efficacy, safety and tolerability of the oral investigational compound, laquinimod, versus placebo in the treatment of RRMS.

The Allegro study completed patient screening at the end of the third quarter. Recruitment of over 1,000 patients at 152 sites throughout North America, Europe and Asia was finalized in November. The completion of recruitment triggers a milestone payment of \$5 million to Active Biotech from Teva Pharmaceutical Industries Ltd.

A second pivotal Phase III clinical trial evaluating laquinimod, called Bravo, is currently enrolling patients globally. The Bravo trial aims to provide risk-benefit data for laquinimod versus Avonex<sup>®</sup>, an available injectable treatment.

Previous data from the phase IIb core study and its 36-week extension period (presented at the World Congress on Treatment and Research in MS in September) demonstrated the rapid onset and sustained efficacy of laquinimod in reducing disease activity, as well as the favorable safety profile of the compound.

For more information on the ongoing laquinimod Phase III clinical program, please visit [www.TevaClinicalTrials.com](http://www.TevaClinicalTrials.com)

or call 1-866-550-0614.

### **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. 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, 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 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. The enrollment goal is approximately 1,200 patients with RRMS.

The global clinical program will include centers throughout the United States as well as centers in Canada, Europe, and Israel. To learn more about Teva's ongoing clinical trials, please visit [www.TevaClinicalTrials.com](http://www.TevaClinicalTrials.com) or call 1-800-840-5601.

### **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<sup>®</sup> 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, 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>, Neurontin<sup>®</sup>, Lotrel<sup>®</sup> and Protonix<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, our ability to successfully identify, consummate and integrate acquisitions, including the pending acquisition 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").*



**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: November 18, 2008

2