

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
April 12, 2011

**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 2011

Commission File Number 0-16174

**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): \_\_\_\_\_

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

**ORAL LAQUINIMOD FOR MULTIPLE SCLEROSIS TREATMENT SIGNIFICANTLY REDUCED DISEASE ACTIVITY AND DISABILITY PROGRESSION WHILE PROVIDING GOOD SAFETY AND TOLERABILITY**

*Teva Announces Updated Time For Webcast To Discuss Study Results On April 11th, 7:00 p.m. EDT*

- Phase III ALLEGRO study met primary endpoint and key secondary endpoints:
  - o 23 percent reduction in annualized relapse rate
  - o 36 percent reduction in sustained disability progression
  - o 33 percent reduction in brain atrophy
  - o Safe and well-tolerated therapy without immunosuppressive effects
- Additional new pre-clinical data demonstrate potential neuroprotective mechanism of action of laquinimod

**Jerusalem, Israel and Lund, Sweden, April 11, 2011** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech (NASDAQ OMX NORDIC: ACTI) announced today results from the two-year Phase III ALLEGRO study of laquinimod, an oral, once-daily, investigational immunomodulator for the treatment of relapsing forms of multiple sclerosis (MS). These data will be presented as late-breaking research at the Annual Meeting of the American Academy of Neurology (AAN).

In the ALLEGRO study, laquinimod showed a statistically significant 23 percent reduction in annualized relapse rate ( $p=0.0024$ ), the primary endpoint, along with a significant 36 percent reduction in the risk of confirmed disability progression, as measured by Expanded Disability Status Scale (EDSS) ( $p=0.0122$ ). Treatment with laquinimod was also associated with a significant reduction in brain tissue loss, as measured by a 33 percent reduction in progression of brain atrophy ( $p<0.0001$ ).

"The ALLEGRO study results are exciting, as they suggest that oral laquinimod is a novel therapeutic option that safely slows MS disease activity and progression," said Principal Investigator, Professor Giancarlo Comi, Director of the Department of Neurology and Institute of Experimental Neurology at the University Vite Salute, San Raffaele, Italy. "Additional pre-clinical data presented at this meeting suggest that oral laquinimod exerts a novel and protective mechanism of action within the central nervous system to significantly reduce the main neurological damage of the disease."

Laquinimod was safe and well-tolerated without immunosuppressive effects. The overall frequencies of adverse events, including incidence of infections, were comparable to those observed in the placebo group. The most commonly reported adverse events were headaches, nasopharyngitis and back pain. The incidence of liver enzyme elevation was higher in laquinimod treated patients; however, these elevations were transient, asymptomatic and reversible. No deaths were reported in laquinimod-treated patients.

The positive ALLEGRO results are supported by new pre-clinical data, also presented at the AAN meeting, that further establish the mechanism of action (MOA) of laquinimod, which led to a reduction in axonal damage, the main determinant of permanent clinical disability in MS. Data from the cuprizone model, designed to investigate the effect on neurodegeneration, independent of inflammation, demonstrated that laquinimod reduced demyelination and axonal damage while preserving more myelin-producing cells. This unique effect suggests a direct decrease in nerve damage in the central nervous system (CNS). Additionally, laquinimod was shown to modulate the brain-derived neurotrophic factor (BDNF) pathway, a key factor in maintaining axonal integrity.

"We are very enthusiastic about the results of the ALLEGRO study, which demonstrated that laquinimod significantly slows the progression of disability, the primary goal of MS treatment. Given the efficacy, safety and tolerability data to date, laquinimod may present a very promising treatment option to the MS community," said Professor Yitzhak Peterburg, Teva's Group Vice President, Global Branded Products.

The second laquinimod Phase III study, BRAVO, is currently ongoing with results anticipated in the third quarter of 2011. Regulatory submissions are planned in the U.S. and the EU following the availability of the BRAVO results.

**CONFERENCE CALL/WEBCAST**

Teva Pharmaceutical Industries Ltd. (Nasdaq: TEVA) will host an audio webcast on April 11<sup>th</sup>, 2011 at 7:00 p.m. EDT to present the results from the Phase III ALLEGRO study of laquinimod. Those interested in listening to the webcast should log on to <http://www.tevapharm.com/financial/> and register for the event (approximately 10 minutes before). The dial-in for this call is 1-800-215-2410 or 617-597-5410 internationally. The conference ID or passcode is 14479443. An archive of the webcast will be available on Teva's website.

## **ABOUT THE ALLEGRO STUDY**

ALLEGRO was a two-year multi-national, multi-center randomized, double blind, placebo-controlled study designed to evaluate the efficacy, safety and tolerability of laquinimod in MS patients. The study was conducted at 139 sites in 24 countries and enrolled 1,106 MS patients. Patients were randomized to receive a once-daily oral dose of 0.6 mg laquinimod or matching placebo. The primary outcome measure was the number of confirmed relapses; secondary measures included confirmed disability progression and changes in MRI active lesions.

Eighty percent of laquinimod and 77 percent of placebo patients completed the two-year study. Patients who completed the ALLEGRO study were offered to join an open-label extension phase, in which they are being treated with laquinimod 0.6 mg daily.

## **ABOUT LAQUINIMOD**

Laquinimod is an oral, once-daily, immunomodulator with a novel mechanism of action being developed for the treatment of MS. The global Phase III clinical development program evaluating oral laquinimod in MS consists of two pivotal studies, ALLEGRO and BRAVO. BRAVO, is a two-year, multi-national, multi-center, randomized, double-blind, parallel-group, placebo-controlled study designed to compare the safety, efficacy and tolerability of a once-daily oral dose of 0.6 mg laquinimod over placebo and to perform a comparative risk-benefit assessment between laquinimod and interferon beta-1a. Enrollment of 1,332 patients at 154 sites in the U.S, Europe, Israel and South Africa was completed in June 2009. BRAVO study results are anticipated in the third quarter of 2011.

In addition to the ongoing MS clinical studies, laquinimod is currently in Phase II development for Crohn's disease and Lupus, and is being studied in other autoimmune diseases.

## **ABOUT 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. Multiple sclerosis is a degenerative disease of the central nervous system in which inflammation and axonal damage and loss result in the development of progressive disability.

## **ABOUT TEVA**

Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's largest generic drug maker, with a global product portfolio of more than 1,450 molecules and a direct presence in 60 countries. Teva's branded businesses focus on neurological, respiratory and women's health therapeutic areas as well as biologics. Teva's leading innovative product, Copaxone<sup>®</sup>, is the number one prescribed treatment for multiple sclerosis. Teva employs approximately 40,000 people around the world and reached \$16.1 billion in net sales in 2010.

## ABOUT ACTIVE BIOTECH

Active Biotech AB (NASDAQ OMX NORDIC: ACTI) is a biotechnology company with focus on autoimmune/inflammatory diseases and cancer. Projects in or entering pivotal phase are laquinimod, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, TASQ for prostate cancer as well as ANYARA for use in cancer targeted therapy, primarily of renal cell cancer. In addition, laquinimod is in Phase II development for Crohn's and Lupus. Further projects in clinical development comprise the two orally administered compounds, 57-57 for SLE & Systemic Sclerosis and RhuDex(TM) 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>, Protonix<sup>®</sup> and Gemzar<sup>®</sup>, the extent to which any manufacturing or quality control problems damage our reputation for high quality production, the effects of competition on sales of our innovative products, especially Copaxone<sup>®</sup> (including potential generic and oral competition for Copaxone<sup>®</sup>), the impact of continuing consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of ratiopharm), interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, intense competition in our specialty pharmaceutical businesses, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, dependence on the effectiveness of our patents and other protections for innovative products, 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, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, our potential exposure to product liability claims to the extent not covered by insurance, the termination or expiration of governmental programs or tax benefits, current economic conditions, any failure to retain key personnel or to attract*

*additional executive and managerial talent, environmental risks and other factors that are discussed in this report and in our other filings with the U.S. Securities and Exchange Commission.*

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

Teva Pharmaceutical Industries Ltd. Web Site: [www.tevapharm.com](http://www.tevapharm.com)

### **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 11, 2011



1