

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
August 02, 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 August 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):

RESULTS OF PHASE III BRAVO TRIAL REINFORCE UNIQUE PROFILE OF LAQUINIMOD FOR MULTIPLE SCLEROSIS TREATMENT

Primary endpoint of reducing annualized relapse rate was not statistically achieved

**Following a standard adjustment, in accordance with a pre-defined sensitivity analysis, laquinimod significantly reduced the annualized relapse rate ( $p=0.026$ )**

**Laquinimod also demonstrated significant reductions in both brain volume loss and the risk of disability progression, while maintaining a favorable safety and tolerability profile**

Regulatory submissions are planned in the U.S. and EU

Teva to host conference call to discuss study results on August 1, 8:30 a.m. EDT

Jerusalem, Israel and Lund, Sweden, August 1, 2011 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech (NASDAQ OMX NORDIC: ACTI) announced today initial results from the Phase III BRAVO study, which was designed to evaluate the efficacy, safety and tolerability of oral laquinimod compared to placebo and to provide a benefit-risk assessment comparing oral laquinimod and a reference arm of injectable Interferon  $\beta$ -1a (Avonex<sup>®</sup>). BRAVO is the second of two pivotal Phase III studies in the clinical development program for laquinimod, an investigational, oral, once-daily therapy for the treatment of relapsing-remitting multiple sclerosis (RRMS). Results showed that the BRAVO study did not achieve its primary endpoint of reducing the annualized relapse rate ( $p=0.075$ ).

The randomization process for BRAVO was adequately performed; however, placebo and treatment study groups showed dissimilarity in two baseline magnetic resonance imaging (MRI) characteristics. According to a standard and pre-specified sensitivity analysis included within the original statistical analysis plan, when this imbalance was corrected laquinimod demonstrated a significant reduction in the annualized relapse rate (21.3%,  $p=0.026$ ), in the risk of disability progression as measured by Expanded Disability Status Scale (EDSS) (33.5%,  $p=0.044$ ) and in brain volume loss (27.5%,  $p<0.0001$ ).

The BRAVO findings support the direct effect of laquinimod within the central nervous system (CNS) and are in line with the results of the first laquinimod Phase III trial, ALLEGRO. Additionally, as in ALLEGRO, the BRAVO study found that laquinimod demonstrated a favorable safety and tolerability profile compared to placebo.

Compared to placebo, treatment with Interferon  $\beta$ -1a reduced annualized relapse rates; however, a reduction in brain tissue loss was not demonstrated and a reduction in the progression of disability did not yield a supportive p value.

The BRAVO study was not designed to provide direct statistical comparisons of efficacy endpoints between the two active arms.

"We are encouraged by the overall outcomes achieved in the laquinimod Phase III clinical development program, and plan to submit applications to regulatory authorities in the U.S. and EU," said **Professor Yitzhak Peterburg, Teva's Group Vice President, Global Branded Products**. "Teva remains committed to the clinical development of laquinimod and is confident that the drug could provide a unique option for the treatment of multiple sclerosis."

"Data from the ALLEGRO and BRAVO studies demonstrated that laquinimod reduced disability and brain tissue loss, two of the most important goals in the treatment of relapsing forms of multiple sclerosis," said **Professor Per Soelberg Sørensen, MD, Head of MS Research Unit, Copenhagen University Hospital, Rigshospitalet, Co-principal investigator of the BRAVO study**. "These effects, coupled with a favorable safety profile and a once-daily dosing regimen create a promising potential treatment for the disease."

Additional analyses of the BRAVO study data are ongoing, and results will be submitted for presentation at a scientific congress later in the year.

#### CONFERENCE CALL/WEBCAST

Teva Pharmaceutical Industries Ltd. will host an audio webcast on August 1, 2011 at 8:30 a.m. EDT to discuss the results from the Phase III BRAVO 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 1-800-299-6183 within the U.S. or 617-801-9713 internationally. The conference ID or passcode is 85409706. An archive of the webcast will be available on Teva's website.

#### ABOUT THE BRAVO STUDY

BRAVO was 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 provide a descriptive comparison of the risk-benefit profiles of laquinimod and interferon beta-1a. The primary outcome measure was to assess the efficacy of 0.6 mg daily dose of laquinimod as measured by the relapse rate. Secondary outcome measures included impact on the accumulation of disability and brain atrophy. The BRAVO study completed enrollment in June 2009, recruiting more 1,331 patients at 153 sites worldwide, including in the U.S., Europe, Russia, Israel and South Africa.

#### 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. In the ALLEGRO study, laquinimod demonstrated a significant positive impact on disease activity, disability progression and MRI measures of inflammation and neurodegeneration, while maintaining a favorable safety and tolerability profile. Specifically, laquinimod showed a statistically significant 23 percent reduction in annualized relapse rate and 36 percent significant reduction in the risk of confirmed disability progression, as measured by EDSS.

In addition to the 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 1,300 molecules and a direct presence in about 60 countries. Teva's branded businesses focus on neurological, respiratory and women's health therapeutic areas as well as biologics. Teva currently employs approximately 42,000 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 version of Protonix®reg, 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®reg (including potential generic and oral competition for Copaxone®reg), the impact of continuing consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of Cephalon), 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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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: August 2, 2011



