TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
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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 December 2010

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 _____

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Website: **www.tevapharm.com**

TEva announces successful results of phase iii study with oral laquinimod for multiple sclerosis

Laquinimod study met primary endpoint of reducing annualized relapse rate

Treatment with laquinimod significantly slowed progression of disability

Laquinimod data showed a favorable safety and tolerability profile

Jerusalem, Israel and Lund, Sweden, December 9, 2010 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech (NASDAQ OMX NORDIC: ACTI) announced today initial results from the two-year Phase III ALLEGRO study, which demonstrated that relapsing-remitting multiple sclerosis (MS) patients treated with 0.6 mg daily oral laquinimod experienced a statistically significant reduction in annualized relapse rate compared to placebo. Additional clinical endpoints, including significant reduction in disability progression, as measured by Expanded Disability Severity Scale (EDSS), were also achieved.

Laquinimod was safe and well-tolerated. The overall frequencies of adverse events were comparable to those observed in the placebo group. No deaths were reported in laquinimod-treated patients. Overall incidence of infections was similar between the two arms of the trial.

"This pivotal study met its primary endpoint while maintaining a very good safety profile," says Principal Investigator, **Professor Giancarlo Comi, Director of the Department of Neurology and Institute of Experimental Neurology at the University Vite Salute, San Raffaele, Italy**. "Laquinimod demonstrated a significant reduction in the progression of disability which may be explained by its unique mechanism of action that includes neuroprotective

properties. Laquinimod may therefore be a promising therapeutic option for the MS community."

"We are very pleased to have achieved this major milestone in the development of oral laquinimod, a novel therapy that can potentially improve the lives of many MS patients in a safe way," said **Shlomo Yanai, Teva's President and Chief Executive Officer.**

Additional analyses of the ALLEGRO study data are ongoing, and detailed results will be submitted for presentation at a leading scientific conference during the first half of 2011.

Laquinimod received Fast Track designation from the U.S. Food and Drug Administration (FDA) in February 2009. The second phase III study, BRAVO is still ongoing with results anticipated in the third quarter of 2011. Regulatory submissions in the U.S. and the EU will then follow.

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.

Following the successful study results, Teva filed a patent application covering the use of laquinimod in slowing the progression of disability in MS patients.

ABOUT LAQUINIMOD

Laquinimod is a novel once-daily, oral immunomodulatory compound being developed as a disease-modifying treatment for MS. The global Phase III clinical development program evaluating oral laquinimod in MS consists of two pivotal studies, ALLEGRO and BRAVO:

The first clinical 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,. Patients who completed the ALLEGRO study are offered to join an open-label extension phase, in which they will be treated with laquinimod 0.6mg daily until the drug is commercially available.

The second clinical study, 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 expected 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

Multiple sclerosis (MS) is the leading cause of neurological disability in young adults. It is estimated that more than 400,000 people in the U.S. 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 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 1,250 molecules and a direct presence in approximately 60 countries. Teva's branded businesses focus on neurology, oncology, respiratory and women's health therapeutic areas as well as biosimilars. Teva's leading innovative product, Copaxone&reg, is the number one prescribed treatment for multiple sclerosis. Teva employs more than 40,000 people around the world and reached $13.9 billion in net sales in 2009.

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 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 successful completion of the

laquinimod trials, receipt of regulatory approvals and commercialization of laquinimod, 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&reg, Lotrel&reg, Protonix&reg and Yaz&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 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 ("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.

Teva Pharmaceutical Industries Ltd. Web Site: 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 December 9, 2010