

TEVA PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
May 17, 2010

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 May 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 _____

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

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For immediate release

TEVA PROVIDES UPDATE ON TALAMPANEL FOR THE TREATMENT OF AMYOTROPHIC LATERAL SCLEROSIS (ALS)

Jerusalem, Israel, May 17, 2010 - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced results from the Phase II ALSTAR trial. The trial was designed to assess efficacy, safety and tolerability of Talampanel (a selective AMPA antagonist) in reducing disease-related functional deterioration in Amyotrophic Lateral Sclerosis (ALS) patients. Results indicate that while Talampanel was safe for ALS patients, the study did not meet its primary endpoint.

"Despite our hopes to advance the treatment of this debilitating disease, Talampanel did not succeed in demonstrating the required efficacy, although safety was established," said Moshe Manor, Teva's Group Vice President, Global Branded Products. "Broadening our innovative pipeline - through internal R&D, licensing and other business development activities - is part of our long term strategy. This outcome has no impact on our 2015 innovative goal. We will continue to pursue the development of innovative treatments, focused on the therapeutic areas of neurology, autoimmunity and oncology."

About the Study

The multinational, multicenter, randomized, double-blind, placebo-controlled, parallel-group, Phase II study was conducted in 25 centers across US, Canada, Europe and Israel and included 559 patients with ALS. Patients were randomized to receive either Talampanel 25mg three times daily, or Talampanel 50mg three times daily or placebo orally for a period of 52 weeks. All patients enrolled in the trial were allowed to use riluzole (83 percent of patients were on riluzole at the beginning of trial) in combination with Talampanel. The primary outcome measure was change from baseline in the revised ALS Functional Rating Scale (ALSFRS-R), a scale for monitoring progression of disability in ALS patients.

About Talampanel

Talampanel is an orally active antagonist of the alpha-amino-3-hydroxy-5-methyl-4-isoxazolepropionate (AMPA) neuronal excitatory glutamate receptor.

About Amyotrophic Lateral Sclerosis (ALS)

ALS, also known as "Lou Gehrig's disease", is a degenerative motor neuron disease that leads to paralysis and ultimately, to death, usually within 3-5 years from disease onset. The cause of death is most often due to respiratory failure. Progressive symptoms of the disease include muscle weakness in limbs, muscle twitching (fasciculation) and cramping, speech impediments, difficulty swallowing and respiratory impairment. Over 10,000 people in the U.S. and Europe are diagnosed with ALS each year. It is estimated that at least 50,000 people worldwide have the disease at any given time.

About Teva

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 15 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.

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 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^{®}, Lotrel^{®}, and Protonix^{®}, current economic conditions, the extent to which any manufacturing or quality control problems damage our reputation for high quality production, the effects of competition on our innovative products, especially Copaxone^{®} sales, dependence on the effectiveness of our patents and other protections for innovative products, especially Copaxone^{®}, the impact of consolidation of our distributors and customers, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, 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, the uncertainty surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, the regulatory environment and changes in the health policies and structures of various countries, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, the effects of reforms in healthcare regulation, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, potential tax liabilities that may arise should our agreements (including intercompany arrangements), be challenged successfully by tax authorities, our ability to successfully identify, consummate and integrate acquisitions and other business combinations (including our pending acquisition of ratiopharm), the potential exposure to product liability claims to

the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, as well as to credit risk, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, our ability to enter into patent litigation settlements and the increased government scrutiny of our agreements with brand companies in both the U.S. and Europe, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, any failure to retain key personnel or to attract additional executive and managerial talent, environmental risks, and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2009, in this report and in our other filings with the U.S. Securities and Exchange Commission ("SEC").

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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 May 17, 2010

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