

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
February 25, 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 February 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): \_\_\_\_\_



longest prospective and continuous evaluation ever conducted in relapsing-remitting multiple sclerosis (RRMS) patients.

The data were published in the February issue of the journal *Multiple Sclerosis*.

The 15-year clinical study demonstrated that more than 80 percent of patients were still walking without assistance despite a mean MS disease duration of 22 years, and two-thirds of patients have not transitioned to secondary progressive MS. Patients who remained in the study over a mean of 15 years showed a reduction in annualized relapse rate (ARR) from baseline as well as minimal increase in Expanded Disability Status Scale (EDSS). On average, the ARR in the ongoing cohort declined from 1.12  $\pm$  0.82 to 0.25  $\pm$  0.34 at the 15-year analysis.

Additionally, the study reinforces the established long-term safety profile associated with Copaxone<sup>®</sup>. The most common adverse events associated with Copaxone<sup>®</sup> were local injection-site reactions and immediate post-injection reactions. No other immune-mediated disorders, infections or malignancies were reported.

"This study is important for the MS community as it further confirms the benefits of continuous long-term use of Copaxone<sup>®</sup> and its ability to effectively slow the natural progression of this disease," said **Corey Ford, M.D.**, Ph.D., primary investigator in the study and Professor of Neurology, Director of the Multiple Sclerosis Specialty Clinic and Assistant Dean for Research at the University of New Mexico Health Sciences Center. "It is encouraging to see such long-term results that further support the well-established benefit-to-risk profile of this treatment relevant to a life-long disease."

"We are pleased to see that results from this study reinforce the long term efficacy and safety of Copaxone<sup>®</sup>," said **Moshe Manor**, Teva's Group Vice President, Global Branded Products. "The longest term study extension further demonstrates Teva's investment in Copaxone<sup>®</sup> and our ongoing commitment to improve the disease course of MS."

This study represents the only prospective, open-label follow-up study designed to evaluate continuous immunomodulatory therapy in RRMS patients. The study, currently in its 19<sup>th</sup> year, was extended to 20 years based on the positive results seen thus far and the interest of the MS community in the long term outcomes of treatments for this life-long disease.

### **About the Study**

The study "Continuous Long-Term Immunomodulatory Therapy in Relapsing Multiple Sclerosis: Results from the 15-Year Analysis of the U.S. Prospective Open-label Study of Glatiramer Acetate," a follow-up to the pivotal, Phase III trial, followed 100 ongoing Copaxone<sup>®</sup> (glatiramer acetate injection) patients starting in 1991. Patients' EDSS scores were evaluated every six months. Confirmed disability progression was defined as  $\geq$ 1.0 EDSS point increase sustained for six months. Patients were classified as "stable/improved" if EDSS score changes were less or equal to 0.5 points. Proportions of patients who reached confirmed thresholds of EDSS 4, 6, or 8 while on Copaxone<sup>®</sup>, and

Kaplan-Meier (KM) estimates of median times to these thresholds, were obtained.

Fifty-seven percent of patients experienced either stabilized or improved EDSS scores, while 65 percent has not yet transitioned to Secondary-Progressive Multiple Sclerosis (SPMS). While being treated with Copaxone<sup>®</sup>, the mITT patients' ARR declined from 1.18+/-0.82 to 0.43+/-0.58/year.

### **About COPAXONE<sup>®</sup>**

Copaxone<sup>®</sup> is indicated for the reduction of the frequency of relapses in RRMS, including patients who have experienced a first clinical episode and have MRI features consistent with multiple sclerosis. The most common side effects of Copaxone<sup>®</sup> are redness, pain, swelling, itching, or a lump at the site of injection, flushing, rash, shortness of breath, and chest pain.

Copaxone<sup>®</sup> (glatiramer acetate injection) is now approved in 51 countries worldwide, including the United States, Canada, Mexico, Australia, Israel, and all European countries. In North America, Copaxone<sup>®</sup> is marketed by Teva Neuroscience, Inc., which is a subsidiary of Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA). In Europe, Copaxone<sup>®</sup> is marketed by Teva Pharmaceutical Industries Ltd. and sanofi-aventis. Copaxone<sup>®</sup> is a registered trademark of Teva Pharmaceutical Industries Ltd.

See additional important information at <http://www.copaxone.com/pi/index.html> or call 1-800-887-8100 for electronic releases. For hardcopy releases, please see enclosed full prescribing information.

### **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 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 Eloxatin<sup>®</sup>, the current economic conditions, 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 effects of competition on our innovative products, especially Copaxone® sales, including potential oral and generic competition for Copaxone®, dependence on the effectiveness of our patents and other protections for innovative products, 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, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, our ability to successfully identify, consummate and integrate acquisitions, the potential exposure to product liability claims to the extent not covered by insurance, our exposure to fluctuations in currency, exchange and interest rates, 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 intensified scrutiny by the U.S. government, the termination or expiration of governmental programs and tax benefits, impairment of intangible assets and goodwill, 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").

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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 February 25 , 2010