

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
September 08, 2009

**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 September 2009

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)**

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**For Immediate Release**

**NEW TEVA DATA HIGHLIGHTS ADVANCES IN MS TREATMENT RESEARCH**

***- Results Presented at Leading Global MS Congress -***

**JERUSALEM, September 8, 2009** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced that new research data furthering the clinical understanding of its diverse multiple sclerosis (MS) treatment franchise will be presented at the 25<sup>th</sup> Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Düsseldorf, Germany, September 9-12, 2009. Featured presentations and abstracts will include new data on COPAXONE<sup>®</sup>, the global leading treatment for relapsing-remitting multiple sclerosis (RRMS), as well as on the company's compounds in advanced development.

"For nearly two decades Teva has supported the MS community and our ongoing commitment to research and development will continue to provide effective MS treatments while maintaining safety as well as contribute to a greater understanding of the disease," said Moshe Manor, Teva's Group Vice President, Global Branded Products. "Our dedication has not only brought forth the world's leading MS treatment, COPAXONE<sup>®</sup>, but we are looking forward to continually support the MS community through our evolving pipeline, led by oral laquinimod."

Teva will present data on the effect of COPAXONE<sup>®</sup> on the Multiple Sclerosis Severity Score (MSSS) from the longest ongoing prospective study of an immunomodulatory therapy in RRMS. In addition, Teva and Active Biotech (NASDAQ OMX NORDIC: ACTI) will present data on laquinimod, its investigational oral, once-daily, immunomodulating compound being developed for the treatment of RRMS. New data on ATL/TV1102, a second generation antisense inhibitor of CD49d, a subunit of VLA-4, for the treatment of RRMS patients, will be presented as well.

***Platform Presentations/Poster Sessions\****

**COPAXONE<sup>®</sup> Clinical Studies**

Characterization of signal transduction pathways involved in glatiramer acetate (copolymer-1, Copaxone)-induced type II monocyte differentiation (Young Researcher's Session I, September 9)

CD161/CCR6 (IL-17 associated) expression in relapsing multiple sclerosis: effect of glatiramer acetate on immune regulation (Poster #276, September 10)

Improvement on the Multiple Sclerosis Severity Score after 10 and 15 years of glatiramer acetate treatment (Poster #415, September 10)

Glatiramer acetate induced Foxp3 regulatory T-cells contribute to its therapeutic effect in experimental autoimmune encephalomyelitis (Poster #638, September 11)

### **Laquinimod**

Anti-inflammatory pathways activated by laquinimod in CD4+, CD8+, CD14+, CD19+ and NK peripheral blood cells subtypes of relapsing-remitting multiple sclerosis patients (Poster #264, September 10)

Reduced inflammation, demyelination and axonal damage after therapeutic laquinimod treatment in experimental autoimmune encephalomyelitis (Poster #441, September 10)

Long-term open extension of oral laquinimod in patients with relapsing multiple sclerosis shows favorable safety and sustained low relapse rate and MRI activity (Poster #443, September 10)

The effect of laquinimod on lymphocyte VLA-4 properties under shear flow conditions (Poster #628, September 11)

Laquinimod induces up-regulation of neurotrophins in serum of patients with relapsing-remitting multiple sclerosis (Poster #783, September 11)

The effect of laquinimod on the distribution of monocyte subsets (Poster #808, September 11)

### **ATL/TV1102**

Prediction of optimal dosing regimen for TV-1102, a novel anti VLA-4 antisense drug (Poster #435, September 10)

\* Does not include all Teva sponsored studies featured at ECTRIMS

### **About COPAXONE<sup>®</sup> (glatiramer acetate injection)**

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, a lump or an indentation at the site of injection, weakness, infection, pain, nausea, joint pain, anxiety, and muscle stiffness.

COPAXONE<sup>®</sup> is now approved in 52 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 Laquinimod**

Laquinimod is a novel once-daily, orally administered immunomodulatory compound that is being developed as a disease-modifying treatment for RRMS. Active Biotech developed laquinimod and licensed it to Teva Pharmaceutical Industries, Ltd. in June 2004. A Phase IIb study in 306 patients was published in *The Lancet* (June 2008) and demonstrated that an oral 0.6 mg dose of laquinimod, administered daily, significantly reduced MRI disease activity by a median of 60 percent (51 percent mean reduction) versus placebo in RRMS patients. In addition, the study showed a favorable trend toward reducing annual relapse rates and the number of relapse-free patients compared with placebo. Treatment was well tolerated, with only some transient and dose-dependent increases in liver enzymes reported.

In addition to the efficacy that laquinimod has shown in Phase II RRMS clinical trials, laquinimod has demonstrated potent therapeutic efficacy in preclinical models of other autoimmune diseases such as rheumatoid arthritis, insulin-dependent diabetes mellitus, Guillain Barré Syndrome, lupus and Inflammatory Bowel Disease. The broad profile of efficacy in animal models of inflammatory diseases suggests that laquinimod affects a pivotal pathway of inflammation and autoimmunity. Laquinimod is currently in Phase II development for Crohn's disease and Teva expects to initiate the clinical development of the compound for Lupus Nephritis in the near future.

### **About ATL/TV1102**

ATL/TV1102 is a second generation antisense inhibitor of CD49d, a subunit of VLA-4 (Very Late Antigen-4) originally developed by ISIS Pharmaceuticals, Inc. (Carlsbad, California), and licensed to Teva Pharmaceutical Industries Ltd. by Antisense Therapeutics Limited (ANP) (Australia).

VLA-4 is a clinically validated target in the treatment of MS inhibiting the trafficking of inflammatory cells to the site of inflammation. Antisense inhibition of VLA-4 has demonstrated positive effects in a number of animal models of inflammatory disease including MS

A Phase IIa trial studying the safety and efficacy of ALT/TV1102 in RRMS patients was completed. The study showed a significant reduction of 54.4 percent in cumulative number of new active lesions in patients taking ATL/TV1102 for 8 weeks, compared to placebo, as measured by MRI. Teva is planning to continue the development of this new molecule to confirm its efficacy and safety.

### **About Teva**

Teva Pharmaceutical Industries Ltd., headquartered in Israel, is among the top 20 pharmaceutical companies in the world and is the world's leading generic pharmaceutical company. The Company develops, manufactures and markets generic and innovative human pharmaceuticals and active pharmaceutical ingredients, as well as animal health pharmaceutical products. Over 80 percent of Teva's sales are in North America and 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> and Protonix<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<sup>®</sup> sales, 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").*

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 September 8 , 2009

