

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
September 16, 2008

**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 2008

Commission File Number 0-16174



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**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): \_\_\_\_\_

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also hereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes \_\_\_\_\_

No   X  

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g(3)-2(b):  
82-\_\_\_\_\_



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Kevin Mannix Teva North America (215) 591-8912

**For Immediate Release**

**TEVA TO PRESENT NEW TREATMENT DATA AT WORLD CONGRESS FOR  
MULTIPLE SCLEROSIS**

**Jerusalem, Israel, September 15, 2008** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced presentations of several new studies at the World Congress on Treatment and Research in Multiple Sclerosis in Montreal. New data will be presented on COPAXONE<sup>®</sup> (glatiramer acetate injection), a leading therapy for relapsing-remitting multiple sclerosis (RRMS) treatment, covering early treatment with COPAXONE<sup>®</sup>, long-term efficacy and safety.

In addition to Teva's post-marketing studies of COPAXONE<sup>®</sup> in RRMS, the company will also present data on oral laquinimod, which is now being investigated in 2 global Phase III studies ([www.tevaclinicaltrials.com](http://www.tevaclinicaltrials.com)) and on ATL/TV1102, a second-generation VLA-4 inhibitor which has recently published positive results from a Phase IIa study in RRMS patients.

Teva's extensive work and continuous investments exemplified by these presentations represents the Company's commitment to research that advances the understanding of MS and its goal to seek improved therapies to address unmet needs within the category. Teva R&D efforts in this area include a breadth of pipeline compounds focused on various areas of discovery which hold promise for the treatment of MS.

*Platform Presentations/Poster Sessions*

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

Treatment with glatiramer acetate protects axons in patients with clinically isolated syndromes: evidence from the PreCISe trial (Presentation # 17, September 18 at 11:40 AM)

Treatment with glatiramer acetate delays conversion to clinically definite multiple sclerosis (CDMS) in patients with clinically isolated syndrome (CIS): subgroup analyses (Presentation # 32, September 18 at 3:30 PM)

Continuous Long-Term Immunomodulatory Therapy in Relapsing Multiple Sclerosis: Results from the 15 year Analysis of the US Prospective Open-label Study of Glatiramer Acetate (Presentation # 44, September 18 at 3:30 PM)

The impact of long-term treatment with disease modifying therapy on disability progression in relapsing-remitting multiple sclerosis patients (Presentation # 26, September 18 at 3:30 PM)

Long-term follow-up of immunomodulatory therapies in early relapsing-remitting multiple sclerosis (Presentation # 57, September 18 at 3:30 PM)

Fatigue in relapsing-remitting multiple sclerosis - assessment of clinical neuropsychological and immunological parameters in patients treated with glatiramer acetate (Presentation # 478, September 19 at 3:30 PM)

Glatiramer Acetate Reduces Multiple Sclerosis Severity: Analysis of Patients from the US Pivotal Studies Using the Multiple Sclerosis Severity Scale (Presentation # 454, September 19 at 3:30 PM)

Short-term Immunosuppression with Mitoxantrone Followed by Long-term Glatiramer Acetate vs. Glatiramer Acetate Alone: Results at 36 Months in Patients with Relapsing-Remitting Multiple Sclerosis (Presentation # 3, September 18 at 3:30 PM)

## **Laquinimod**

Oral Laquinimod in Patients with Relapsing-Remitting Multiple Sclerosis: 9-month double-blind active extension of the Multi-center, Randomized, Double-blind, Parallel-group Placebo-controlled Study (Presentation # 31, September 18 at 3:30 PM)

Laquinimod given before and after disease onset reduces inflammatory cell infiltration and demyelination in experimental autoimmune encephalomyelitis (Presentation # 842, September 19 at 3:30 PM)

### **ATL/TV1102**

VLA-4 antisense: an oligonucleotide targeting VLA-4 mRNA (ATL1102) significantly reduces new active lesions in patients with relapsing-remitting multiple sclerosis (Presentation # 81, late-breaking news, September 20 at 9:15 AM)

### **About COPAXONE<sup>®</sup>**

COPAXONE<sup>®</sup> 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.

COPAXONE<sup>®</sup> is indicated for the reduction of the frequency of relapses in RRMS. 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.

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 (OMX NORDIC:ACTI) developed laquinimod and licensed it to Teva Pharmaceutical Industries, Ltd. in June 2004. A Phase IIb study in 306 patients was recently published in *The Lancet* and demonstrated that an oral 0.6 mg dose of laquinimod, administered daily, significantly reduced magnetic resonance images (MRI) disease activity by a median of 60 percent versus placebo in RRMS patients. Laquinimod also showed consistent and robust effect on all secondary MRI endpoints. 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. Over 460 MS patients have received laquinimod in various Phase I-II clinical trials.



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 Barr 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. Teva expects to initiate the clinical development of laquinimod for Crohn's disease and 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, 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 impact of consolidation of our distributors and customers, potential liability for sales of generic products prior to a final resolution of outstanding patent litigation, including that relating to the generic versions of Allegra® , Neurontin® , Lotrel® and Protonix®, the effects of competition on our innovative products, especially Copaxone® sales, the impact of pharmaceutical industry regulation and pending legislation that could affect the pharmaceutical industry, the difficulty of predicting U.S. Food and Drug Administration, European Medicines Agency and other regulatory authority approvals, the regulatory environment and changes in the health policies and structures of various countries, our ability to achieve expected results through our innovative R&D efforts, our ability to successfully identify, consummate and integrate acquisitions, including the pending acquisition of Barr Pharmaceuticals Inc., potential exposure to product liability claims to the extent not covered by insurance, dependence on the effectiveness of our patents and other protections for innovative products, significant operations worldwide that may be adversely affected by terrorism, political or economical instability or major hostilities, supply interruptions or delays that could result from the complex manufacturing of our products and our global supply chain, environmental risks, fluctuations in currency, exchange and interest rates, 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)

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## **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 15, 2008