

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
April 23, 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 April 2009

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

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

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



Contact: **Elana Holzman** Teva Pharmaceutical Industries Ltd. 972 (3) 926-7554  
**Kevin Mannix** Teva North America (215) 591-8912

**For Immediate Release**

## **Teva to Present New Data on its Innovative Therapies for Multiple Sclerosis and Parkinson`s Disease at the Upcoming 2009 American Academy of Neurology Annual Meeting**

JERUSALEM, April 22, 2009 --Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) today announced that several new studies addressing the Company`s innovative central nervous system (CNS) portfolio will be presented at the 61<sup>st</sup> Annual American Academy of Neurology meeting in Seattle starting April 28, 2009.

Long-term COPAXONE<sup>®</sup> (glatiramer acetate injection) data include an analysis demonstrating neuroprotection in relapsing-remitting multiple sclerosis (RRMS) patients.

New information on the treatment of Parkinson`s disease (PD) with AZILECT<sup>®</sup> (rasagiline tablets) include endpoints from the ADAGIO study; data demonstrating selectivity of MAO-B inhibition at maximum recommended dosing and the affect of treatment on non-motor symptoms in patients with early disease.

Several studies exploring the mechanism of action of laquinimod, an investigational oral, once-daily, immunomodulating compound being developed for the treatment of RRMS, will also be presented at the meeting. One such study on laquinimod has been selected for presentation during the 2009 Scientific Topics Highlights program of the conference. Laquinimod recently received Fast Track designation from the U.S. Food and Drug Administration (FDA).

In addition, clinical data will be presented on the investigational compound ATL/TV-1102, a second generation antisense inhibitor of CD49d, a subunit of VLA-4, for the treatment of RRMS patients. This data has also been selected for presentation during the 2009 Scientific Topics Highlights program.

"Teva`s unwavering commitment to address patient needs is evident in the continuous research and development of an innovative neurology portfolio including safe, effective and tolerable treatments," said Moshe Manor, Teva`s Vice President, Global Branded Products.

*Platform Presentations/Poster Sessions*

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

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[P05.129] Comparison of Multiple Sclerosis (MS) Relapses and Total Medical Costs for Users of Glatiramer Acetate and Beta Interferons: Two-Year Analysis of a U.S. Managed Care Database (Poster session V: Multiple Sclerosis: Outcomes and Scales II, April 29, 11:30 AM - 2:30 PM, Room 6E)

[P03.083] Six-Year Prospective Multi-Voxel Brain MRS Study of Two Cohorts in RRMS To Examine the Effect of Glatiramer Acetate on Neuronal/Axonal Metabolic Injury (Poster session III: Multiple Sclerosis: Imaging, April 28, 4:00 PM - 7:00 PM, Room 6E)

[P09.097] Predictive Biomarkers of Clinical Response to Glatiramer Acetate (GA) Therapy in Multiple Sclerosis (MS) (Poster session IX: Multiple Sclerosis: Immunology II, April 30, 4:00 PM - 7:00 PM, Room 6E) do we have to include

[P09.100] Impaired CD4+ T Effector: T Regulatory Cell Conversion in Relapsing Multiple Sclerosis: Reversal by Treatment with Glatiramer Acetate (Poster session IX: Multiple Sclerosis: Immunology II, April 30, 4:00 PM - 7:00 PM, Room 6E)

[P01.124] Immunological Responses to Different Doses of Glatiramer Acetate in MS: Analyses from the FORTE Trial (Poster session I: Multiple Sclerosis: Immunology I, April 28, 7:00 AM - 10:00 AM, Room 6E)

[P08.045] Alteration of B Cell Cytokine and Growth Factors in Experimental Autoimmune Encephalomyelitis by Glatiramer Acetate (Poster session VIII: Multiple Sclerosis: Animal Models, April 30, 11:30 AM - 2:30 PM, Room 6E)

[P02.031] A Beneficial Effect of Glatiramer Acetate (GA, COPAXONE<sup>®</sup>) in Experimental Autoimmune Neuritis (Poster session II: Peripheral Nerve I, April 28, 11:30 AM - 2:30 PM, Room 6E)

[P01.123] Gene Expression Profiles Following One-Year Treatment with Glatiramer Acetate 20mg and 40mg (GA, COPAXONE<sup>®</sup>) in Relapsing-Remitting Multiple Sclerosis Patients (Poster session I: Multiple Sclerosis: Immunology I, April 28, 7:00 AM - 10:00 AM, Room 6E)

**AZILECT<sup>®</sup> (rasagiline tablets)**

[P06.154] Rasagiline 1 mg/Day Provides Benefits in the Progression of Non-Motor Symptoms in Patients with Early Parkinson's Disease (Poster session VI: Treatment of Parkinson's Disease, April 29, 4:00 PM - 7:00 PM, Room 6E)

[P06.155] A Clinical Pharmacology Study To Determine the Selective and Non-Selective Doses of the Monoamine Oxidase Type B (MAO-B) Inhibitor, Rasagiline (Poster Session VI: Treatment of Parkinson's Disease, April 29, 4:00 PM - 7:00 PM, Room 6E)

[S43.001] The ADAGIO Study: Secondary and Additional Endpoints (Scientific Sessions: Evaluation and Treatment of Parkinson's Disease, April 30, 1:30 PM - 3:30 PM, Room 6A)

**Laquinimod**

[S47.008] The Effect of Laquinimod on Lymphocyte VLA-4 Properties under Shear Flow Conditions (Scientific session: Multiple Sclerosis: Immunology III, April 30, 1:30 PM - 3:30 PM, Room 605/610)

[P01.120] Down Regulation of Antigen Presentation and Inflammatory Pathways by Laquinimod in Cultured Peripheral Blood Mononuclear Cells of Untreated Multiple Sclerosis Patients and Healthy Subjects (Poster session I: Multiple Sclerosis: Immunology, April 28, 7:00 AM - 10:00 AM, Room 6E)

Teva to Present New Data on its Innovative Therapies for Multiple Sclerosis and Parkinson's Disease at the Upcom

[P08.051] Laquinimod Inhibits MOG-Induced Experimental Autoimmune Encephalomyelitis (EAE) in CD4+CD25+ Regulatory T-Cell Depleted Mice (Poster session VIII: Multiple Sclerosis: Animal Models, April 30, 11:30 AM - 2:30 PM, Room 6E)

[P01.113] Effect of Laquinimod on the Dendritic Cell Compartment (Poster session I: Multiple Sclerosis: Immunology I, April 28, 7:00 AM - 10:00 AM, Room 6E)

#### **ATL/TV1102**

[S11.001] VLA-4 Antisense An Oligonucleotide Targeting VLA-4 mRNA (ATL1102) Significantly Reduces New Active Lesions in Patients with RR-MS (Scientific session: Multiple Sclerosis: Clinical Therapeutics and Interventions, April 28, 3:45 PM - 5:00 PM, Room 6B)

#### **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 AZILECT<sup>®</sup> (rasagiline tablets)**

AZILECT<sup>®</sup> 1mg tablets are indicated for the treatment of the signs and symptoms of Parkinson's disease both as initial therapy alone and to be added to levodopa later in the disease. AZILECT<sup>®</sup> 1mg tablets are currently available in 36 countries, including the US, Canada, Israel, Mexico, and all EU countries.

Teva has a long-term agreement for the joint development and marketing of AZILECT<sup>®</sup> in Europe and some additional markets with H. Lundbeck A/S. In North America, AZILECT<sup>®</sup> is marketed by Teva's wholly-owned subsidiary Teva Neuroscience ([www.tevaneuro.com](http://www.tevaneuro.com)).



See additional important information at <http://www.azilect.com/PrescribingInformation.pdf.ashx>. For hardcopy releases, please see enclosed full prescribing information.

AZILECT<sup>®</sup> is indicated for the treatment of the signs and symptoms of Parkinson's disease (PD) both as initial therapy alone and to be added to levodopa later in the disease.

### **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. Results from a Phase IIb study in 306 patients were published in June 2008 in *The Lancet* and reported 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 in the number of relapse-free patients compared with placebo. Treatment was well tolerated, with some transient and dose-dependent increases in liver enzymes reported, without clinically-evident liver damage.

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 Crohn's disease, rheumatoid arthritis, insulin-dependent diabetes mellitus, Guillain Barré Syndrome, and Lupus. The broad profile of efficacy in animal models of inflammatory diseases suggests that laquinimod affects a pivotal pathway of inflammation and autoimmunity. Teva has also initiated a clinical study to evaluate laquinimod for Crohn's disease and expects to initiate the clinical development of laquinimod 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 ATL/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, including the integration of Barr Pharmaceuticals, Inc., 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)

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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: April 22, 2009

