

TEVA PHARMACEUTICAL INDUSTRIES LTD  
Form 6-K  
October 06, 2010

**TEVA TO PRESENT NEW DATA ON COPAXONE<sup>®</sup> AND LAQUINIMOD AT THE 26<sup>th</sup> ANNUAL ECTRIMS CONGRESS**

*Studies Showcase Teva's Ongoing Commitment to Multiple Sclerosis Research*

**Jerusalem, Israel, October 6, 2010** - Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) announced today that more than 20 scientific abstracts supporting its multiple sclerosis (MS) franchise will be presented at the 26<sup>th</sup> Annual Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in Gothenburg, Sweden, October 13-16, 2010.

Key featured data include:

Results from the five-year extension of the PreCISe study that further evaluate the value of early versus delayed treatment with Copaxone<sup>®</sup> (glatiramer acetate injection) in patients who have experienced a first clinical episode and have magnetic resonance imaging (MRI) features consistent with MS.

Data from pre-clinical and animal model studies demonstrating evidence of the presumed mechanism of action (MOA), the unique immunomodulatory effect, as well as the potential neuroprotective properties of laquinimod, Teva's investigational, once-daily oral compound for the treatment of RRMS.

Results demonstrating the associations between the development of Neutralizing Antibodies (NAbs) and Binding Antibodies (BAbs) during interferon beta treatments, and the potential impact of NAbs and BAbs testing on clinical outcome measures in MS.

-

**Platform Presentations/Poster Sessions:**

**Copaxone<sup>&reg</sup>**

**[P413] Evolution of T1 hypointense lesions in relapsing-remitting multiple sclerosis patients treated with glatiramer acetate. (Poster Session: Immunomodulation 1, October 14, 3:30pm-5:00pm CET) *R. Zivadinov, S. Hussein, N. Bergsland, M. Dwyer***

**[P901] Clinical markers of therapeutic response with interferons and with glatiramer acetate and the long term impact on relapse-induced disability. (Poster Session: Long Term Treatment Monitoring 2, October 15, 3:30pm-5:00pm CET) *A. Carrá, P. Onaha, G. Rojas, G. Imhoff-Jullier, C. Vrech***

[P 986] Benefit of early treatment with glatiramer acetate: MRI results from the 5-year prospectively planned follow up in patients with clinically isolated syndrome enrolled in the PreCISe study. (Poster Session: Late Breaking News, October 15, 3:30pm-5:00pm CET) *M. Filippi, M.A. Rocca, E. Perego, F. Agosta, A. Meani, O. Bajenaru, A. Carra, I. Elovaara, F. Fazekas, H.P. Hartung, J. Hillert, J. King, S. Komoly, C. Lubetzki, X. Montalban, K.M. Myhr, M. M Ravnborg, P. Rieckmann, D. Wynn, C. Young, G. Comi for the PreCISe study group*

**[135, Congress Hall] Benefit of early treatment with glatiramer acetate (COPAXONE<sup>®</sup>): results from the 5-year prospectively planned follow up in patients with clinically isolated syndrome from the PreCISe study. (Parallel Session: Late Breaking News, October 16, 8:45am-9:00am CET) *G. Comi, V. Martinelli, M. Rodegher, L. Moiola, O. Bajenaru, A. Carra, I. Elovaara, F.***

***Fazekas, H.P. Hartung, J. Hillert, J. King, S. Komoly, C. Lubetzki, X. Montalban, K.M. Myhr, M. Ravnborg, P. Rieckmann, D. Wynn, C. Young, M. Filippi***

#### Laquinimod

[P251] Laquinimod rescue therapy in mice with experimental autoimmune encephalomyelitis. (Poster Session: Experimental Models 1, October 14, 2010, 3:30pm-5:00pm CET) *C. Wegner, R. Pförtner, W. Brück (Göttingen, DE)*

[P881] Laquinimod ameliorates experimental autoimmune encephalomyelitis via BDNF-dependent mechanisms. (Poster Session: Neuroprotection 2, October 15, 3:30pm-5:00pm CET) *J. Thöne, D. Lee, S. Seubert, L. Hayardeny, R. Linker, R. Gold*

[P882] Differential activity of laquinimod on production of inflammatory molecules and neurotrophic factors by human microglia and macrophages. (Poster Session: Neuroprotection 2, October 15<sup>th</sup>, 3:30pm-5:00pm CET) *C. Silva, J. Wang, M. Mishra, V.W. Yong*

[P885] Laquinimod prevents the inflammation-induced derangement of neurogenic niches in experimental autoimmune encephalomyelitis mice. (Poster Session: Neuroprotection 2, October 15, 3:30pm-5:00pm CET) *F. Ruffini, A. Bergamaschi, C. Marinaro, R. De Ceglia, L. Muzio, R. Furlan, L. Hayardeny, G. Comi, G. Martino*

-

#### Neutralizing Antibodies (NAbs)

Fazekas, H.P. Hartung, J. Hillert, J. King, S. Komoly, C. Lubetzki, X. Montalban, K.M. Myhr, M. Ravnborg, P.

[P462] Relationship between binding and neutralizing antibodies in patients taking high dose interferon MS therapy. (Poster Session: Immunomodulation 1, October 14, 3:30pm-5:00pm CET) *E. Fox, A. Goodman, C. Markowitz, R. Murray, B. Green*

[P889] Analysis of a relationship between clinical outcomes and neutralizing antibody titres in multiple sclerosis patients treated with interferon beta. (Poster Session: Long Term Treatment Monitoring 2, October 15, 3:30pm-5:00pm CET) *E. Fox, C. Markowitz, R. Murray, B. Green, A. Goodman*

[P960] Myxovirus resistance protein A RNA expression correlates with binding and neutralizing antibody levels in multiple sclerosis patients treated with interferon beta. (Poster Session: Biomarkers 2, October 15, 3:30pm-5:00pm CET) *A. Goodman, R. Murray, B. Green, E. Fox, C. Markowitz*

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, Russia, 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 the global market-leading RRMS treatment.

See additional important information at <http://www.copaxone.com/pdf/PrescribingInformation.pdf> or call 1-800-887-8100 for electronic releases.

## **ABOUT LAQUINIMOD**

Laquinimod is an investigational, novel, once-daily oral immunomodulator 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* and demonstrated that an oral 0.6 mg dose of laquinimod, administered daily, significantly reduced MRI disease activity by 60 percent 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.

Two pivotal, global Phase III studies of laquinimod for the treatment of RRMS, ALLEGRO and BRAVO, are nearing completion. ALLEGRO, a 24-month multinational, double-blind, placebo-controlled study, designed to evaluate the efficacy, safety and tolerability of laquinimod versus placebo in the treatment of RRMS, enrolled 1,106 patients and data from the study are expected in Q1 2011. BRAVO, a multinational, multi-center, randomized, parallel-group study designed to evaluate laquinimod compared to placebo, as well as to provide risk-benefit data for laquinimod compared to a currently available injectable treatment, Avonex<sup>®</sup>, has enrolled 1,332 patients and will be complete in Q3 2011.

In addition to the ongoing RRMS clinical studies, laquinimod is currently in Phase II development for Crohn's disease and Lupus, and is being studied in other autoimmune diseases.

## **ABOUT TEVA**

Teva Pharmaceutical Industries Ltd. (NASDAQ:TEVA) is a leading global pharmaceutical company, committed to increasing access to high-quality healthcare by developing, producing and marketing affordable generic drugs as well as innovative and specialty pharmaceuticals and active pharmaceutical ingredients. Headquartered in Israel, Teva is the world's largest generic drug maker, with a global product portfolio of more than 1,250 molecules and a direct presence in approximately 60 countries. Teva's branded businesses focus on neurological, respiratory and women's health therapeutic areas as well as biologics. Teva's leading innovative product, Copaxone<sup>®</sup>, is the number one prescribed treatment for multiple sclerosis. Teva employs more than 40,000 people around the world and reached \$13.9 billion in net sales in 2009.

**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®reg, Lotrel®reg, Protonix®reg and Yaz®reg, the extent to which any manufacturing or quality control problems damage our reputation for high quality production, the effects of competition on sales of our innovative products, especially Copaxone®reg (including potential generic and oral competition for Copaxone®reg), the impact of continuing consolidation of our distributors and customers, our ability to identify, consummate and successfully integrate acquisitions (including the acquisition of ratiopharm), interruptions in our supply chain or problems with our information technology systems that adversely affect our complex manufacturing processes, intense competition in our specialty pharmaceutical businesses, any failures to comply with the complex Medicare and Medicaid reporting and payment obligations, our exposure to currency fluctuations and restrictions as well as credit risks, the effects of reforms in healthcare regulation, adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations, increased government scrutiny in both the U.S. and Europe of our agreements with brand companies, dependence on the effectiveness of our patents and other protections for innovative products, 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, uncertainties surrounding the legislative and regulatory pathway for the registration and approval of biotechnology-based products, potentially significant impairments of intangible assets and goodwill, potential increases in tax liabilities resulting from challenges to our intercompany arrangements, our potential exposure to product liability claims to the extent not covered by insurance, the termination or expiration of governmental programs or tax benefits, current economic conditions, any failure to retain key personnel or to attract additional executive and managerial talent, 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")*

###

