

TEVA PHARMACEUTICAL INDUSTRIES LTD  
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## ORAL LAQUINIMOD DEMONSTRATED SUSTAINED EFFICACY AND SAFETY IN PATIENTS WITH MULTIPLE SCLEROSIS

- Positive benefit-risk profile of laquinimod sustained *in Phase II extension study*
- *52 percent reduction (p=0.0006) in mean number of gadolinium-enhancing (GdE) T1 lesions*
- *Results from pivotal Phase III studies, ALLEGRO and BRAVO, anticipated in 2011*

**Jerusalem, Israel, September 20, 2010** -- Teva Pharmaceutical Industries Ltd. (NASDAQ: TEVA) and Active Biotech (NASDAQ OMX NORDIC: ACTI) today announced results from a 36-week active extension study evaluating two doses of laquinimod, an investigational, once-daily oral immunomodulator, for the treatment of *relapsing remitting multiple sclerosis (RRMS)*. The double-blind, multinational study demonstrated the sustained positive benefit-risk profile of laquinimod, which was shown to reduce Gd-enhancing (GdE) T1 lesions, while maintaining a good safety profile. These findings were published online by the journal *Multiple Sclerosis*.

Patients originally randomized to placebo in the core Phase II study, LAQ/5062, (published in *The Lancet*\*) were re-randomized to either 0.3 mg or 0.6 mg laquinimod for the extension study, while patients originally randomized to active treatment continued with the same treatment assignment for an additional 36 weeks. Patients switching from placebo to an active treatment of laquinimod showed a 52 percent reduction in the *mean number of GdE lesions* (p=0.0006), *a marker of disease activity*. In patients initially randomized to 0.6 mg laquinimod, the reduction of MRI activity was maintained. Additionally, treatment with laquinimod was associated with a sustained reduction in relapse rate, no evidence of immunosuppression and good safety and tolerability profile.

"The results from this extension study confirm the balanced efficacy, safety, and tolerability profile seen with laquinimod to date," explains Giancarlo Comi, M.D., the lead study author and the Director of the Department of Neurology and Institute of Experimental Neurology at the University Vite Salute, San Raffaele. "We look forward to the results of the Phase III ALLEGRO and BRAVO studies in 2011, and the potential of this novel agent to address the current unmet need for MS patients seeking a safe, effective and well tolerated oral therapy."

Laquinimod received Fast Track designation from the U.S. Food and Drug Administration (FDA) in February 2009. Two global Phase III clinical studies, ALLEGRO and BRAVO are currently ongoing, with results anticipated during Q1 and Q3 2011, respectively.

\* Comi G. et al. (2008). Effect of laquinimod on MRI-monitored disease activity in patients with relapsing remitting multiple sclerosis: a multicentre, randomized, double-blind, placebo-controlled phase IIb study. *The Lancet*; 371:2085-92.

## **ABOUT THE STUDY**

The multinational, double-blind, 36-week extension of the placebo-controlled Phase IIb laquinimod study was conducted in 9 countries at 51 sites. Two hundred thirty-nine (93 percent) patients completed the extension phase of the study and 222 (87.1 percent) had a final scan. GdE lesions were significantly reduced for patients switching from placebo to 0.3 or 0.6mg doses (52 percent,  $p = 0.0006$ ). In patients initially randomized to 0.6 mg, the reduction of MRI activity observed in the placebo-controlled phase was maintained in the extension. The proportion of GdE-free patients for those who switched from placebo increased from a baseline of 31 percent to 47 percent at the end of the extension phase ( $p = 0.01$ ). No new adverse events emerged during the extension study. The incidence rate of liver enzymes elevation observed in the LAQ/5062 core study decreased in the extension phase.

## **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.

## **ABOUT ACTIVE BIOTECH**

Active Biotech AB (NASDAQ OMX NORDIC: ACTI) is a biotechnology company with focus on autoimmune/inflammatory diseases and cancer. Projects in or entering pivotal phase are laquinimod, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis, TASQ

for prostate cancer as well as ANYARA for use in cancer targeted therapy, primarily of renal cell cancer. In addition, laquinimod is in Phase II development for Crohn`s and Lupus. Further projects in clinical development comprise the two orally administered compounds, 57-57 for SLE & Systemic Sclerosis and RhuDex(TM) for RA. Please visit [www.activebiotech.com](http://www.activebiotech.com) for more information.

**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").*

**Active Biotech`s Safe Harbor Statement in Accordance with the Swedish Securities Market Act:**

*This press release contains certain forward-looking statements. Such forward-looking statements involve known and unknown risks, uncertainties and other important factors that could cause the actual results, performance or achievements of the company, or industry results, to differ materially from any future results, performance or achievement implied by the forward-looking statements. The company does not undertake any obligation to update or publicly release any revisions to forward-looking statements to reflect events, circumstances or changes in expectations after the date of this press release.*

*Active Biotech is obligated to publish the information contained in this press release in accordance with the Swedish Securities Market Act.*

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**Teva Contacts:**

<b>Investor Relations:</b>	<b>Media:</b>
Elana Holzman <i>Teva Pharmaceutical Industries Ltd.</i> 972 (3) 926-7554	Yossi Koren <i>Teva Pharmaceutical Industries Ltd.</i> 972 (3) 926-7590
Kevin Mannix <i>Teva North America</i> (215) 591-8912	Denise Bradley <i>Teva North America</i> (215) 591-8974

**Active Biotech Contacts:**

Tomas Leanderson	+46-46-19-20-95
Göran Forsberg	+46-46-19-11-54