



# Teva and Active Biotech Announce Expansion of Laquinimod Clinical Development Program with New Trial in Primary Progressive Multiple Sclerosis and First Patient Screened in Huntington's Disease Trial

ARPEGGIO and LEGATO-HD trials will further evaluate the effect of laquinimod in neurodegenerative diseases

Jerusalem & Lund, Sweden – November 4, 2014 – Teva Pharmaceutical Industries Ltd. (NYSE:TEVA) and Active Biotech (NASDAQ OMX NORDIC:ACTI) today announced the expansion of the laquinimod clinical development program with the initiation of the ARPEGGIO trial, which will evaluate the potential of laquinimod to treat primary progressive multiple sclerosis (PPMS). Additionally, Teva has screened the first patient in the LEGATO-HD trial, which will evaluate laquinimod in Huntington's disease. Currently, there are no approved therapies available for the treatment of PPMS or the treatment of Huntington's disease, beyond symptom management.

"Teva prides itself in striving to help patients with neurodegenerative diseases through research and innovation," said Michael Hayden, M.D., Ph.D., President of Global R&D and Chief Scientific Officer at Teva Pharmaceutical Industries, Ltd. "Laquinimod has been shown to modulate several significant pathways common to key neurodegenerative disease. More specifically, it modulates the immune cell lineages in the periphery and in the CNS. We look forward to the results from both of these studies."

The ARPEGGIO study will evaluate the efficacy, safety and tolerability of laquinimod in patients with PPMS with a primary endpoint of percent brain volume change (PBVC) through MRI analysis. PPMS is characterized by the worsening of neurologic function without distinct relapses (also called attacks or exacerbations). Approximately 15 percent of MS patients fall into the PPMS category.

The LEGATO-HD study will evaluate the efficacy, safety and tolerability of once-daily oral laquinimod as a potential treatment for adult patients with Huntington's disease. The primary endpoint for LEGATO-HD is change from baseline in the Unified Huntington's Disease Rating Scale-Total Motor Scale (UHDRS-TMS) as defined by the sum of the scores of all UHDRS-TMS sub-items after 12 months of treatment. Huntington's disease is caused by a genetically-programmed degeneration of brain cells in select areas of the brain, which results in uncontrolled movements, loss of intellectual faculties and personality and emotional disturbances. Huntington's disease affects about five to seven people per 100,000 in Western countries.

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For further details on the Phase II ARPEGGIO and LEGATO-HD studies, please search laquinimod at ClinicalTrials.gov.

### **About ARPEGGIO**

The study, <u>A</u> <u>R</u>andomized <u>P</u>lacebo-controlled Trial <u>E</u>valuating Laquinimod in PPMS, <u>G</u>auging <u>G</u>radations <u>I</u>n MRI and Clinical <u>O</u>utcomes (ARPEGGIO) is a multinational, multicenter, randomized, double-blind, parallel-group, placebo-controlled, Phase II clinical trial.

ARPEGGIO is intended to serve as a proof-of-concept study for potential treatment with laquinimod in PPMS. The trial will evaluate two doses of laquinimod (0.6 and 1.5mg/day) in PPMS compared to placebo. The primary endpoint of the study is brain atrophy as defined by PBVC from baseline to week 48. Secondary endpoints include time to confirmed disability progression, the number of new T2 lesions and change in the Brief International Cognitive Assessment for Multiple Sclerosis (BICAMS) score. ARPEGGIO has an estimated completion date of H2 2017.

#### **About LEGATO-HD**

LEGATO-HD (<u>Laquinimod</u> <u>Efficacy</u> and Safety in a <u>GlobAl</u> <u>Trial</u> <u>Of</u> <u>HD</u>) is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of laquinimod treatment at doses of 0.5, 1.0, and 1.5 mg/day in 400 adult Huntington's disease patients between the ages of 21-55. Ancillary studies will evaluate microglia activation, neuronal integrity, and peripheral inflammatory biomarkers. LEGATO-HD has an estimated completion date of H1 2017.

The primary endpoint of LEGATO-HD is change from baseline in the Unified Huntington's Disease Rating Scale-Total Motor Scale (UHDRS-TMS) as defined by the sum of the scores of all UHDRS-TMS sub-items after 12 months of treatment. Secondary endpoints will measure brain atrophy, cognition, clinical global impression and functional capacity.

### **About Laquinimod**

Laquinimod is a once-daily oral, investigational, CNS-active immunomodulator with a novel mechanism of action being developed for the treatment of relapsing-remitting MS (RRMS), progressive MS and Huntington's disease. The global, Phase III, clinical development program evaluating laquinimod in MS includes two completed pivotal studies, ALLEGRO and BRAVO (both 0.6mg/day). A third Phase III trial, CONCERTO, is currently ongoing and evaluating two doses of laquinimod (0.6mg and 1.2mg/day) in approximately 2,100 patients for up to 24 months. The primary outcome measure is time to three-month confirmed-disability progression as measured by the Expanded Disability Status Scale (EDSS).

In the ALLEGRO and BRAVO trials, adverse reactions observed included headache, abdominal pain, back and neck pain, appendicitis, and mild, asymptomatic laboratory abnormalities, including liver enzyme elevations, hematological changes and elevation of CRP or fibrinogen levels.

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### **About Teva**

Teva Pharmaceutical Industries Ltd. (NYSE: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 leading generic drug maker, with a global product portfolio of more than 1,000 molecules, sold in more than 100 countries, and with a direct presence in about 60 countries. Teva's specialty medicine businesses focus on CNS, including pain, respiratory, oncology, and women's health therapeutic areas as well as biologics. Teva currently employs approximately 45,000 people around the world and reached \$20.3 billion in net revenues in 2013.

### **About Active Biotech**

Active Biotech AB (NASDAQ OMX NORDIC:ACTI) is a biotechnology company with focus on autoimmune/inflammatory diseases and cancer. In pivotal phase is laquinimod, an orally administered small molecule with unique immunomodulatory properties for the treatment of multiple sclerosis. Also tasquinimod for the treatment of prostate cancer, with a unique mode of action, is in pivotal phase. In addition, laquinimod has concluded Phase II development for Crohn's and Lupus. The company has two additional projects in clinical development, ANYARA primarily for the treatment of renal cell cancer and the orally administered compound paquinimod (57-57) for systemic sclerosis. Please visit <a href="https://www.activebiotech.com">www.activebiotech.com</a> for more information.

## Safe Harbor Statement under the U.S. Private Securities Litigation Reform Act of 1995:

This release contains forward-looking statements, which are based on management's current beliefs and expectations. Such statements 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 develop and commercialize additional pharmaceutical products; competition for our innovative products, especially Copaxone® (including competition from orally-administered alternatives, as well as from potential generic versions); the possibility of material fines, penalties and other sanctions and other adverse consequences arising out of our ongoing FCPA investigations and related matters; our ability to achieve expected results from the research and development efforts invested in our pipeline of specialty and other products; our ability to reduce operating expenses to the extent and during the timeframe intended by our cost reduction program; our ability to successfully pursue and consummate suitable acquisitions or licensing opportunities; the extent to which any manufacturing or quality control problems damage our reputation for quality production and require costly remediation; our potential exposure to product liability claims that are not covered by insurance; increased government scrutiny in both the U.S. and Europe of our patent settlement agreements; our exposure to currency fluctuations and restrictions as well as credit risks; the effectiveness of our patents and other measures to protect the intellectual property rights of our specialty medicines; the effects of reforms in healthcare regulation and pharmaceutical pricing, reimbursement and coverage;

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governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; uncertainties related to our recent management changes; the effects of increased leverage and our resulting reliance on access to the capital markets; any failure to recruit or retain executives or other key personnel; adverse effects of political or economical instability, major hostilities or acts of terrorism on our significant worldwide operations; interruptions in our supply chain or problems with internal or third-party information technology systems that adversely affect our complex manufacturing processes; significant disruptions of our information technology systems or breaches of our data security; competition for our generic products, both from other pharmaceutical companies and as a result of increased governmental pricing pressures; competition for our specialty pharmaceutical businesses from companies with greater resources and capabilities; decreased opportunities to obtain U.S. market exclusivity for significant new generic products; potential liability for sales of generic products prior to a final resolution of outstanding patent litigation; any failures to comply with complex Medicare and Medicaid reporting and payment obligations; the impact of continuing consolidation of our distributors and customers; significant impairment charges relating to intangible assets and goodwill; the potential for significant tax liabilities; the effect on our overall effective tax rate of the termination or expiration of governmental programs or tax benefits, or of a change in our business; variations in patent laws that may adversely affect our ability to manufacture our products in the most efficient manner; environmental risks; and other factors that are discussed in our Annual Report on Form 20-F for the year ended December 31, 2013 and in our other filings with the U.S. Securities and Exchange Commission. Forward-looking statements speak only as of the date on which they are made and we assume no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

### 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. This information was provided to the media for publication 02:00 pm CET on November 4, 2014.

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