Press Release

# Teva and Active Biotech Announce Discontinuation of Higher Doses of Laquinimod in Two Multiple Sclerosis Trials

## CONCERTO and ARPEGGIO Trials Continue Study of Lower-dose Laquinimod

**Jerusalem & Lund, Sweden – January 4, 2016 –** Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) and Active Biotech (NASDAQ Stockholm: ACTI) today announced the discontinuation of higher doses of laquinimod in two ongoing studies in multiple sclerosis after the occurrence of cardiovascular events, none of which was fatal, in eight patients.

The change comes at the recommendation of the data monitoring committee (DMC) overseeing two active clinical studies in MS. The DMC identified an imbalance in the number of cardiovascular events in the studies. Seven events were observed in patients receiving laquinimod daily at 1.2mg for treatment of relapsing-remitting MS (RRMS) in the CONCERTO trial. No events occurred in the 0.6mg or placebo groups. CONCERTO has 2,199 patients with 3,070 years of patient experience. One event was observed in the 1.5mg daily-dose arm of the ARPEGGIO trial in primary-progressive MS (PPMS). ARPEGGIO has enrolled 191 patients and has 35 years of patient experience. Teva is notifying trial sites to discontinue the higher doses immediately in both trials and will encourage participants to continue follow ups.

Both trials, CONCERTO and ARPEGGIO, are continuing the lower-dose arms (0.6mg daily), and participants in the trials will be provided with an update to confirm re-consent for participation. The DMC did not identify a cardiovascular signal with the lower dose but recommended long-term monitoring. Teva has completed large trials and is conducting long-term extension studies at the 0.6mg dose currently without cardiovascular concerns.

Through a licensing agreement, Teva has global rights to develop and commercialize laquinimod, a small-molecule entity discovered by Active Biotech.

**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), primary-progressive MS (PPMS) and Huntington disease.

Details about clinical trials with laquinimod can be found at clinicaltrials.gov. Trials mentioned in this release and the clinicaltrials.gov reference number follow:


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- CONCERTO (RRMS) -- NCT01707992
- ARPEGGIO (PPMS ) -- NCT02284568
- ALLEGRO extension (RRMS) – NCT00988052
- BRAVO extension (RRMS) - NCT01047319
- LAQ/5063-OL (RRMS) - NCT00745615

**About Teva**

Teva Pharmaceutical Industries Ltd. (NYSE and TASE: TEVA) is a leading global pharmaceutical company that delivers high-quality, patient-centric healthcare solutions to millions of patients every day. Headquartered in Israel, Teva is the world's largest generic medicines producer, leveraging its portfolio of more than 1,000 molecules to produce a wide range of generic products in nearly every therapeutic area. In specialty medicines, Teva has a world-leading position in innovative treatments for disorders of the central nervous system, including pain, as well as a strong portfolio of respiratory products. Teva integrates its generics and specialty capabilities in its global research and development division to create new ways of addressing unmet patient needs by combining drug development capabilities with devices, services and technologies. Teva's net revenues in 2014 amounted to $20.3 billion. For more information, visit www.tevapharm.com.

**About Active Biotech**

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company with focus on neurodegenerative/inflammatory diseases and cancer. Laquinimod, an orally administered small molecule with unique immunomodulatory properties, is in pivotal phase III development for the treatment of relapsing-remitting multiple sclerosis. Also, laquinimod is in phase II development for the treatment of primary-progressive multiple sclerosis and Huntington disease. Furthermore, commercial activities are ongoing for the projects ISI, ANYARA and paquinimod. Please visit 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 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 develop and commercialize additional pharmaceutical products; competition for our specialty products, especially Copaxone® (including competition from orally-administered alternatives, as well as from generic equivalents such as the recently launched Sandoz product) and our ability to continue to migrate users to our 40 mg/mL version and maintain patients on that version; our ability to identify and successfully bid for suitable acquisition targets or licensing opportunities (such as our pending acquisitions of Allergan's generic business and Rimsa), or to consummate and integrate acquisitions; the possibility of material fines, penalties and other sanctions and other adverse consequences arising out of our*


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*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; the extent to which any manufacturing or quality control problems damage our reputation for quality production and require costly remediation; 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, confidentiality agreements 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; governmental investigations into sales and marketing practices, particularly for our specialty pharmaceutical products; adverse effects of political or economic 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; the impact of continuing consolidation of our distributors and customers; decreased opportunities to obtain U.S. market exclusivity for significant new generic products; potential liability in the U.S., Europe and other markets for sales of generic products prior to a final resolution of outstanding patent litigation; our potential exposure to product liability claims that are not covered by insurance; any failure to recruit or retain key personnel, or to attract additional executive and managerial talent; any failures to comply with complex Medicare and Medicaid reporting and payment obligations; significant impairment charges relating to intangible assets, goodwill and property, plant and equipment; the effects of increased leverage and our resulting reliance on access to the capital markets; potentially significant increases in 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, 2014 and in our other filings with the U.S. Securities and Exchange Commission.*

**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 and/or the Financial Instruments Trading Act. This information was provided to the media for publication at 15:00 CET on Jan 4, 2016.*


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