Active Biotech update on laquinimod Development:

The U.S, Food and Drug administration rescinds the Special Protocol Assessment for laquinimod

Lund, September 19, 2016 - Active Biotech (Nasdaq Stockholm: ACTI) provided an update today on laquinimod which is being developed in multiple sclerosis (MS) and Huntington's disease (HD) by Teva Pharmaceutical Industries, Ltd. The U.S. Food and Drug Administration (FDA) has informed Teva that the Special Protocol Assessment (SPA) for the Phase III CONCERTO clinical trial evaluating laquinimod in relapsing remitting multiple sclerosis (RRMS) was rescinded.

Both companies confirmed in January 2016 that the highest dose arms in two MS trials and one trial in HD were discontinued at the recommendation of the Data Monitoring Committees (DMC). In February, 2016, Teva submitted to the FDA an amendment to the SPA to account for this change. However, per FDA regulatory process, the SPA was rescinded as all changes must be agreed to prior to implementation of the change. This requirement could not be fulfilled in the current case, since the DMC recommendation triggered an immediate action to withdraw the 1.2 mg dose for the treatment of RRMS in the interest of patient safety.

The CONCERTO trial continues with one dose (0.6mg/day) vs. placebo on the original schedule, and Teva plans to use this pivotal trial to support filing for marketing approval for laquinimod in the US and EU, as previously communicated. No change is anticipated in the trial's completion date.

Teva has completed two Phase III trials with the 0.6mg daily dose in RRMS and continues long-term extension studies of laquinimod at this dose. Laquinimod is currently being studied in RRMS, primary progressive MS (PPMS) and Huntington disease (HD).

For further information, please contact:

Tomas Leanderson, President and CEO
Tel: +46 46 19 20 95

Hans Kolam, CFO
Tel: +46 46 19 20 44

Active Biotech AB
(Corp. Reg. No. 556223-9227)
Box 724, SE-220 07 Lund
Tel: +46 46 19 20 00
Fax: +46 46 19 11 05

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 3 development for the treatment of relapsing remitting multiple sclerosis. Also, laquinimod is in Phase 2 development for the treatment of primary progressive multiple sclerosis and Huntington's disease. Furthermore, commercial activities are conducted for the tasquinimod, SILC, ANYARA and paquinimod projects. Please visit www.activebiotech.com for more information.*

This information is information that Active Biotech AB is obliged to make public pursuant to the EU Market Abuse Regulation. This information was submitted for publication, through the agency of the contact person set out above, at 08.30 a.m. CET on September 19 2016.