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Active Biotech confirms positive clinical safety profile of laquinimod eye drops

Lund, January 30, 2023 - Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced the completion of the phase I clinical study testing the safety and tolerability of the newly developed laquinimod eye drop formulation in healthy subjects. According to the results, the eye drop was safe and well tolerated both at single ascending doses and after repeated doses for up to 21 days. No serious adverse events were reported.

“There is an unmet medical need for new effective treatments with a beneficial safety and tolerability profile to be used in inflammatory eye disorders such as non-infectious uveitis, a sight-threatening eye disease. The preliminary results of this study are encouraging, with no safety concerns or local toxicity issues with the laquinimod eye drop at the dosing regimens tested,” said Dr Gerhard Garhöfer, Principal Investigator for the study in Vienna, Austria.

Laquinimod is being developed as a new treatment for inflammatory eye disorders, and preclinical data suggest that laquinimod may have a therapeutic effect when given as a capsule or as a topical treatment onto the eye. Active Biotech has developed an eye drop formulation of laquinimod with the aim to use it for treatment initially in patients with non-infectious uveitis.

“Preclinical data has shown that laquinimod has the potential to be used as a treatment option in severe inflammatory eye diseases. With the safety profile established the next step will be to start a clinical study with laquinimod in patients” said Erik Vahtola, CMO of Active Biotech.

The study was a randomized, double-masked, placebo-controlled phase I study to determine the safety and tolerability and establish a safe and tolerable dose for continued development of laquinimod eye drops after single and repeated dosing in healthy subjects. Secondary aims included the assessment of ocular toxicity and pharmacokinetics of laquinimod.

The complete data set from the study is currently being analyzed, and the full study results will be reported in H1 2023.

For more information about the study, see **www.clinicaltrials.gov** ref. NCT05187403

For further information, please contact:

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About laquinimod

Laquinimod is a first-in-class immunomodulator that induces immune tolerance and reduces the pro-inflammatory and angiogenic response by targeting of the myeloid cell compartment. Laquinimod is developed as a new treatment for inflammatory eye disorders in the first step non-infectious uveitis. Laquinimod was previously studied in patients with neurodegenerative and inflammatory diseases, including a phase III randomized study program in multiple sclerosis (MS) patients. The clinical safety and tolerability of laquinimod is well known and preclinical data in disease models support the use of laquinimod for treatment of severe eye disorder including uveitis and eye disorders with abnormal vascularization.

About Active Biotech

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company that deploys its extensive knowledge base and portfolio of compounds to develop first-in-class immunomodulatory treatments for specialist oncology and immunology indications with a high unmet medical need and significant commercial potential. Following a portfolio refocus, the business model of Active Biotech aims to advance projects to the clinical development phase and then further develop the programs internally or pursue in partnership. Active Biotech currently holds three projects in its portfolio: The wholly owned small molecule immunomodulators, tasquinimod and laquinimod, both having a mode of actions that includes modulation of myeloid immune cell function, are targeted towards hematological malignancies and inflammatory eye disorders, respectively. Tasquinimod, is in clinical phase Ib/IIa for treatment of multiple myeloma. Laquinimod is in a clinical phase I study with a topical ophthalmic formulation, to be followed by phase II-study for treatment of non-infectious uveitis. Naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, is in a phase Ib/II clinical program in patients with advanced solid tumors. Please visit **www.activebiotech.com** for more information.

This information is information that Active Biotech is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-01-30 08:30 CET.

Attachments

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