03 APRIL 2024 08:30:00 CEST

Active Biotech announces start of enrollment to the clinical phase I biodistribution study with laquinimod eye drops

Lund, April 3, 2024 - Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced that the clinical phase I biodistribution study Safety, Tolerability, and Distribution of Laquinimod Eye Drops: The LION Study (clinicaltrials.gov NCT06161415) with laquinimod eye drops is now recruiting patients following the approval from the Food and Drug Administration (FDA) and the Institutional Review Board at Stanford University School of Medicine.

The LION study will evaluate whether laquinimod reaches the posterior chamber of the eye to support further development in patients with Non-Anterior-Non-Infectious Uveitis (NA-NIU). Subjects will be dosed with laquinimod eye drops before elective vitrectomy and thereafter samples including vitreous, anterior chamber fluid and plasma will be analysed for laquinimod concentration. Active Biotech supports the study with the Investigational Medicinal Product and related costs.

The study is supported by preclinical data where laquinimod was shown to distribute into the posterior segment of the eye following daily instillations of laquinimod eye drops. The recently completed phase I clinical study in healthy subjects showed no safety or tolerability concerns with daily instillations up to 21 days. The biodistribution study consists of a dose-escalation part and an optional masked, randomized dose-comparison part. Results from the study will be reported during 2024.

Global Ophthalmic Research Center (GORC), Los Altos, CA, US, is the LION study administrative sponsor, and it will be conducted in collaboration with clinician scientists at the Byers Eye Institute, Stanford University, Palo Alto, CA, led by Principal Investigator Professor Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology, Medicine and Pediatrics, Stanford University School of Medicine.

Dr. Nguyen is known for his innovative work in early proof-of-concept, first-in-human clinical trials to evaluate potential pharmacotherapeutic agents for retinal vascular and uveitic diseases. He is a member of various prestigious professional organizations including the Club Jules Gonin, the Macula Society, the Retina Society, the American Ophthalmological Society, and the International Uveitis Study Group, among others. He serves as President of the International Ocular Inflammation Society as well as Executive Vice President of the Foster Ocular Immunology Society.

For further information, please contact:

Helén Tuvesson, *CEO*, +46 46 19 21 56, **helen.tuvesson@activebiotech.com**
Hans Kolam, *CFO*, +46 46 19 20 44, **hans.kolam@activebiotech.com**

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 clinical development for treatment of non-infectious uveitis and a clinical phase I study with a topical ophthalmic formulation has been concluded. 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.

About laquinimod

Laquinimod is a first-in-class immunomodulator that promotes 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 the treatment of severe eye disorders including uveitis and eye disorders with abnormal vascularization.

Attachments

Active Biotech announces start of enrollment to the clinical phase I biodistribution study with laquinimod eye drops