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Active Biotech enters into collaboration agreement for clinical ocular biodistribution study with laquinimod

Lund, December 5, 2023 – Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced that it has entered into a clinical trial collaboration agreement with the Global Ophthalmic Research Center (GORC), Los Altos, CA, US for a phase I clinical ocular biodistribution study with laquinimod eye drops.

GORC is the study administrative sponsor and the clinical trial, known as the LION Study, will be conducted in collaboration with clinician scientists at the Byers Eye Institute, Stanford University (Palo Alto, CA, USA) led by Principal Investigator Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology, Medicine and Pediatrics, Stanford University School of Medicine. Active Biotech will support the LION Study with the Investigational Medicinal Product (IMP) and related costs.

"The biodistribution study is a logical step in the clinical development of laquinimod eye drops with the aim to bring a well-tolerated treatment option to patients with a serious disease. Patients with non-anterior non-infectious uveitis (NA-NIU) require high doses of immunosuppressive treatments and there is an urgent need for novel therapies which could reduce the need for systemic corticosteroids. We are very pleased to start the collaboration with renowned and experienced organizations such as GORC and Byers Eye Institute at Stanford in taking this important step", said Erik Vahtola, MD, PhD, Chief Medical Officer at Active Biotech.

The biodistribution study aims to evaluate whether laquinimod reaches the posterior chamber of the eye to support further development in patients with NA-NIU. The study is supported by preclinical data from rabbits where laquinimod was shown to distribute into the posterior segment of the eye following daily instillations of laquinimod eye drops. Furthermore, the completed phase I clinical study in healthy subjects showed no safety or tolerability concerns with daily instillations up to 21 days.

GORC, established in 2017 is a not-for-profit organization that assists clinicians, scientists and researchers to advance diagnosis and therapy for ophthalmic diseases. Professor and Principal Investigator Quan Dong Nguyen has served as principal investigator on multiple clinical trials for macular edema (due to diabetes and uveitis), neovascular age-related macular degeneration (AMD) and ocular inflammatory and uveitic diseases.

Professor 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. Dr. Nguyen currently 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

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