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Positive results from Active Biotech's clinical phase I LION study to be presented at AAO 2025 in October

Lund, September 10, 2025 – Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced a presentation will be featured highlighting the positive results from the ocular biodistribution LION study at the prestigious American Academy of Ophthalmology 129th Annual Meeting (AAO 2025) in Orlando, Florida, October 18-20.

The poster presentation, titled *Safety, Tolerability and Distribution of Topical Laquinimod Eye Drops, an Innovative Immunomodulator Targeting Aryl Hydrocarbon Receptor: The LION Study*, emphasizes, among other findings, that topical laquinimod was well tolerated with no toxicity or drug related adverse events at doses resulting in therapeutically relevant concentrations of laquinimod in the posterior parts of the eye.

"These results support further investigation of laquinimod's therapeutic potential in inflammatory eye diseases. There is unmet need for effective, steroid-sparing topical anti-inflammatory agents with favorable safety profiles that can reach the posterior segment", said Dr. Dalia Mohammed El Feky, a Visiting Scholar at the Byers Eye Institute, Stanford University School of Medicine, Palo Alto, CA.

The results from the LION study show that daily dose levels of either 0.6, 1.2 mg and 1.8 mg resulted in dose related intraocular concentrations of laquinimod, which reached a therapeutically relevant level in both the vitreous humor and anterior chamber. Patients scheduled to undergo pars plana vitrectomy for various indications were administered laquinimod daily as eye drops during a 14-day preoperative period.

Laquinimod administered as eye drops at the chosen daily dose levels was safe and well tolerated for the period of administration studied, and no dose-limiting toxicities were reported in any of the subjects.

"Laquinimod, has a distinct immunomodulatory mechanism compared to conventional immunosuppressants. Its effects go beyond simple suppression, as it promotes a durable shift from an autoimmune-prone landscape to a self-tolerant, balanced state and enhances neuronal protection and repair mechanisms in addition to its anti-inflammatory properties. Given these unique immunological and neuroprotective effects along with its ability to reach the posterior segment, laquinimod holds a significant promise for investigation in patients with uveitis as well as patients with macular edema secondary to inflammation (MESI)" said Quan Đông Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology, Medicine and Pediatrics at the Byers Eye Institute and the Stanford University School of Medicine (Palo Alto, USA) and Principal Investigator of the LION Study.

Previously this year, on June 27, the top-line results from the LION study were discussed by Dr. El Feky as an oral presentation at the 2025 International Ocular Inflammation Society (IOIS) Congress, the largest scientific meeting in the field of uveitis and ocular inflammation in the world, in Rio de Janeiro, Brazil.

Active Biotech's focus for the laquinimod program is now directed towards identifying the best development partner for the continued clinical development of laquinimod in eye disorders.

The abstract is available online on **https://aao.apprisor.org/apsSession.cfm?id=PO718**

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About Active Biotech

Active Biotech AB (publ) (NASDAQ Stockholm: ACTI) is a biotechnology company that develops first-in-class immunomodulatory treatments for oncology and immunology indications with a high unmet medical need and significant commercial potential. Active Biotech currently holds three projects in its portfolio, of which tasquinimod and laquinimod are wholly owned small molecule immunomodulators with a mode of action that includes modulation of myeloid immune cell function. The projects are in clinical development for hematological malignancies and inflammatory eye disorders, respectively. The company's core focus is on the development of tasquinimod in myelofibrosis, a rare blood cancer, where clinical proof-of-concept studies have been initiated. A clinical Phase Ib/IIa study in multiple myeloma has been concluded. Laquinimod is in clinical development for the treatment of non-infectious uveitis. A clinical phase I program with a topical ophthalmic formulation has been performed to support phase II development together with a partner. The third pipeline project is naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, which 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.
For more information about the study please see **clinicaltrials.gov** NCT06161415.

About the LION study

A proprietary formulation of laquinimod for corneal application was developed, taking the specific physico-chemical characteristics of this agent into account, to facilitate that a clinically relevant intraocular therapeutic concentration of laquinimod can be obtained.
The LION-study (*Safety, Tolerability, and Distribution of Topical **L**aquinimod Eye Drops, an **I**nnovative Immunomodulat**O**r Targeting Aryl Hydrocarbo**N** Receptor* NCT06161415) which was conducted by principal investigator Professor Dr Nguyen at the Byers Eye Institute, Stanford University, Palo Alto, CA, US, aimed to evaluate safety and tolerability and ocular biodistribution of laquinimod when administered as escalating doses of eye drops (stage 1) and a randomized, controlled comparison of two doses (stage 2) in subjects undergoing elective vitrectomy. It was decided to close the study after stage 1 based on the positive safety, tolerability and biodistribution results.

Attachments

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