05 MAY 2025 09:00:00 CEST

Active Biotech reports positive top-line results from the LION study on ocular absorption and distribution of laquinimod in the eye

- *Daily treatment with laquinimod eye drops resulted in dose related and therapeutically relevant concentrations of laquinimod in both the anterior and posterior parts of the eye.*
- *Laquinimod eye drop treatment was safe and tolerable during 14 days' administration*

Lund, May 5, 2025 – Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced positive top-line results from the clinical phase I LION study. Patients scheduled to undergo pars plana vitrectomy for various elective indications were administered laquinimod daily as eye drops during a 14-day preoperative period.

The top-line results from the LION study (*Safety, Tolerability, and Distribution of Topical **L**aquinimod Eye Drops, an **I**nnovative Immunomodulat**O**r Targeting Aryl Hydrocarbo**N** Receptor*) show that daily dose levels of either 0.6, 1.2 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. 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.

"It is tremendously satisfying to learn that topical laquinimod, even at a low dose, can penetrate into the anterior chamber and, more importantly, the vitreous of human eyes," 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.

Importantly, these results demonstrate that laquinimod, when administered topically by patients as an eye drop, can yield intra-ocular concentrations in the posterior parts of the eye, which are known to affect ongoing inflammatory processes. These data support a continued development of laquinimod eye drops for patients with non-infectious inflammatory eye-diseases.

"The potential applications of a topical formulation and delivery that reaches the vitreous and likely posterior segment are quite significant and can lead to very important and novel therapeutic implications. Our talented team at Byers and Stanford is very excited with the outcomes of the study," said Dr. Nguyen.

The LION study will be given as an oral presentation at the upcoming 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, on June 26, 2025.

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.

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 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 has been initiated. Also ongoing is a clinical Phase Ib/IIa study in multiple myeloma. Laquinimod is in clinical development for the treatment of non-infectious uveitis. A clinical phase I program with a topical ophthalmic formulation is ongoing 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 study (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.

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 2025-05-05 09:00 CEST.

Attachments

Active Biotech reports positive top-line results from the LION study on ocular absorption and distribution of laquinimod in the eye