

## FIRST SUBJECT DOSED IN PHASE I CLINICAL STUDY WITH EYE-DROP FORMULATION OF LAQUINIMOD

**Lund, December 10, 2021 - Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced that the first subject has been dosed in the phase I clinical study of the newly developed eye-drop formulation of the company's candidate drug laquinimod.**

Laquinimod is being developed as a new treatment for non-infectious non-anterior uveitis and has the potential to be used in the first line treatment as an add-on to steroids as well as in the second line treatment for patients that have failed steroid treatment.

Preclinical data suggest that laquinimod may influence inflammatory eye diseases when given both as a tablet and directly onto the eye. Active Biotech has developed an eye-drop formulation of laquinimod with the aim to use it for the treatment of inflammatory eye diseases, initially in patients with non-infectious non-anterior uveitis. These are patients who lack sufficiently effective and safe treatments and in addition, there is currently no eye-drop treatment available.

A preclinical program shows that the laquinimod eye-drop is safe and well tolerated, and the safety of this new formulation will now be tested in a phase I clinical study in healthy subjects. The primary endpoint of the study is to determine the safety and tolerability of laquinimod eye-drops after single and repeat doses. Secondary endpoints include eye toxicity and pharmacokinetics.

I am happy to report that we have initiated the clinical development of the new formulation of laquinimod and I look forward to review the results from this initial safety study. Laquinimod has the potential to be used in the treatment of serious eye diseases, which is underscored by preclinical data. In the next step we will continue the clinical investigation of laquinimod in patients with uveitis, with the goal to provide a new treatment to this sight-threatening eye disease" said Helén Tuvešson, CEO of Active Biotech.

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*This information is information that Active Biotech AB is obliged to make public pursuant to the EU Market Abuse Regulation. This information was submitted for publication, through the agency of the contact person set out above, at 08.30 am CET on December 10, 2021.*

**About laquinimod**

Laquinimod is a first-in-class immunomodulator that targets antigen presenting cells and skews them into a tolerogenic phenotype, leading to induction of an anti-inflammatory immune response. Laquinimod is developed as a new treatment for inflammatory eye disorders in the first step non-infectious non-anterior 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 serious eye disorder including uveitis.

#### **About uveitis**

Uveitis is the inflammation of the uveal tract (iris, ciliary body, and choroid), but can also lead to inflammation of nearby tissues, such as the retina, the optic nerve, and the vitreous humor. The uvea is crucial for the delivery of oxygen and nutrients to the eye tissues, and inflammation of uvea can cause serious tissue damage to the eye with symptoms including general vision problems and a risk of blindness. The treatment options for patients with non-infectious non-anterior uveitis are limited and mostly patients are treated with long-term, high dose steroid therapy. Still, many patients fail in achieving disease control, or cannot continue corticosteroids due to severe side effects. Thus, there is a need for safer therapies that can reduce or replace use of steroids and a treatment that could be administered topically to minimize systemic adverse effects.

#### **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: Naptumomab, a targeted anti-cancer immunotherapy, partnered to NeoTX Therapeutics, is in a phase Ib/II clinical program in patients with advanced solid tumors. The 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 advancing to a clinical phase I study with a topical ophthalmic formulation, to be followed by phase II for treatment of non-infectious uveitis. Please visit [www.activebiotech.com](http://www.activebiotech.com) for more information.