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Active Biotech provides update on the scheduled clinical program for 2024

Lund, December 22, 2023 - Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced an update to the timelines of its scheduled clinical studies to be initiated in 2024, backed by the company's recently completed successful financing round.

The next step in the development of the drug candidate laquinimod will be a clinical ocular biodistribution study of the newly developed eye drop formulation. This study aims to evaluate whether laquinimod reaches the posterior chamber of the eye, to support further development in patients with non-infectious, non-anterior uveitis.

The study will be performed in collaboration with clinician scientists at the Byers Eye Institute, Palo Alto, CA, led by Principal Investigator Quan Dong Nguyen, MD, MSc, FAAO, FARVO, FASRS, Professor of Ophthalmology, Stanford University School of Medicine. The study is progressing towards a scheduled start in Q1 2024, and the preparations including an internal review and a regulatory approval process are advancing according to plan.

As communicated earlier, Active Biotech will focus its project pipeline on the development of tasquinimod in myelofibrosis, a blood cancer with high medical need, and the company plans to start clinical phase II proof-of-concept studies in Europe and in the US in 2024.

The start of the European study within the HOVON network, with full external funding by Oncode, which previously was planned to start in the latter part of Q1 2024, will not start until Q3 2024, due to administrative procedures of these multicenter trials in Germany and the Netherlands. It is a monotherapy study of tasquinimod in patients ineligible to receive JAK inhibitor treatment, with Professor Rebekka Schneider-Kramann as its Lead Principal Investigator.

In parallel, a clinical phase II study in myelofibrosis in the US is prepared in collaboration with the University of Texas MD Anderson Cancer Center. This study will evaluate tasquinimod alone and in combination with the JAK inhibitor ruxolitinib. It is currently undergoing internal review at MD Anderson prior to regulatory submission. The review procedure is advancing ahead of plan, and we currently see a possible start of the study already in mid-2024.

"Our preparations for the scheduled clinical studies are steadily moving forward, and we will deliver according to what was established in the recently concluded rights issue. I look forward to an exciting 2024," said Helén Tuvesson, CEO of Active Biotech AB.

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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.

Attachments

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