

First cohort under amended protocol successfully completes safety evaluation in HOVON 172 MF clinical study of tasquinimod in myelofibrosis

Lund, Sweden - October 13, 2026 Active Biotech (NASDAQ STOCKHOLM: ACTI) today announced that the first safety cohort of three patients enrolled under the amended protocol has successfully completed the 6-week safety evaluation period in the European phase Ib/II proof-of-concept study evaluating tasquinimod in patients with myelofibrosis (HOVON172 MF, the TasqForce study). In accordance with the study protocol, enrolment will now continue in three additional patients to further confirm safety and tolerability and to establish the recommended Phase II dose regimen of tasquinimod. The study is performed in a collaboration between Active Biotech, Oncode and HOVON, which is the legal sponsor of the study.

“The encouraging safety and tolerability observed in the first cohort support the continued clinical evaluation of tasquinimod in myelofibrosis. I look forward to the study’s continued progress and the generation of additional clinical data,” said Dr Martina Crysandt, Co-Investigator of the study.

“The study is now enrolling according to plan following approval of the protocol amendment. Data from this safety cohort support the tolerability of the revised dosing regimen and enrolment will resume as planned. Once safety has been confirmed in the next three patients, we anticipate reporting the recommended Phase II dose regimen,” said Dr Erik Vahtola, CMO Active Biotech.

“The successful completion of the first cohort under the amended protocol represents an important milestone for the HOVON 172 MF study,” said Marleen Breems, CEO of HOVON. “As legal sponsor, HOVON is committed to advancing investigator-initiated clinical research for patients with myelofibrosis who have limited treatment options. This study demonstrates the value of collaboration between academic investigators, Oncode Institute and industry partners in bringing innovative therapies closer to patients.”

The HOVON 172 MF (HO172) study is an open-label Phase Ib/II trial evaluating tasquinimod as monotherapy in patients with myelofibrosis (MF) who are refractory or intolerant to JAK inhibitor treatment. Following implementation of the amended study protocol, the first patient was enrolled in July 2026. We now report safety and tolerability data from the first three patients treated according to the amended dosing schedule.

During the six-week dose-limiting toxicity (DLT) observation period, one serious adverse event (SAE), which also qualified as a DLT, was observed. The event resolved following appropriate medical management and the patient remains on study. No additional DLTs were observed, and all three patients continue treatment. In line with the study protocol, enrolment will now proceed with three additional patients at the current dose schedule.

Based on the available safety data, the observed SAE does not alter the overall safety assessment of tasquinimod. Patients in the study continue to be closely monitored, with supportive care measures and dose modifications implemented as needed in accordance with the protocol to ensure patient safety.

About the HOVON 172 MF study

The HOVON 172 MF clinical study is an open-label, phase Ib/II study evaluating tasquinimod as monotherapy in patients with myelofibrosis who are refractory or intolerant to JAK inhibitor therapy. The phase Ib part of the study aims to determine the safety and tolerability and the Recommended Phase II Dose (RP2D) regimen. Once the RP2D is established, the Phase II portion will evaluate preliminary efficacy and further characterize the safety profile of tasquinimod in patients with MF. The study is conducted within the Stichting Haemato-Oncologie Volwassenen Nederland (HOVON) network of clinical centers across the Netherlands and Germany, with HOVON acting as the legal sponsor and responsible for overall study oversight and conduct.

The study originates from translational research conducted within Oncode Institute and is supported by Oncode Institute's Clinical Proof-of-Concept program.

Active Biotech holds an exclusive global license from Oncode Institute for the development of tasquinimod in myelofibrosis and supplies the investigational medicinal product for the study.

For more information on the study, see clinicaltrials.gov (NCT06605586) and HOVON website www.hovon.nl

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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. 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. Laquinimod is in 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. 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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