

ALLIGATOR RECEIVES POSITIVE SCIENTIFIC ADVICE FROM EMA ON PHASE 3 TRIAL OF MITAZALIMAB

Lund, Sweden, 17 June 2025 — Alligator Bioscience (Nasdaq Stockholm: ATORX), a clinical-stage biotechnology company developing tumor-directed immunotherapies, today announced that the European Medicines Agency (EMA) has provided positive scientific advice supporting the overall design of the planned Phase 3 study of mitazalimab in metastatic pancreatic cancer.

The advice confirms that the proposed Phase 3 study of mitazalimab in combination with mFOLFIRINOX is appropriately designed to support future marketing authorization application. The guidance confirms that the information submitted supports mitazalimab advancement to registrational trials, and Alligator is continuing preparations for trial initiation in line with regulatory input.

This regulatory feedback represents another key milestone in the late-stage development of mitazalimab and complements the recently announced **confirmation by the U.S. Food and Drug Administration (FDA) of the Phase 3 dose.**

"We are very pleased with EMA's endorsement of our Phase 3 trial design and mitazalimab's Phase 3 readiness, confirming its path to regulatory approval in Europe," said Søren Bregenholt, CEO of Alligator Bioscience. "This advice from EMA aligns very well with previous input from FDA thus enabling a single global Phase 3 study leading to mitazalimab's potential registration as a new treatment for patients with metastatic pancreatic cancer in these major territories."

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The information was submitted for publication, through the agency of the contact person set out above, at 8:45 a.m. CEST on 17 June 2025.

About Alligator Bioscience

Alligator is a clinical-stage biotechnology company developing tumor-directed immuno-oncology antibody drugs focused on the CD40 receptor. This validated approach promotes priming of tumor-specific T cells and reversing the immunosuppressive nature of the tumor microenvironment, with significant potential benefits for cancer patients across multiple types of cancer. The Company's lead drug candidate mitazalimab is currently in preparation for Phase 3 development, and has previously presented unprecedented survival data at 24-months follow up in first-line metastatic pancreatic cancer patients in the Phase 2 trial OPTIMIZE-1.

Alligator is listed on Nasdaq Stockholm (ATORX) and headquartered in Lund, Sweden.

For more information, please visit alligatorbioscience.com.

Attachments

Alligator receives positive scientific advice from EMA on Phase 3 trial of mitazalimab