

ALLIGATOR ANNOUNCES FIRST PATIENT DOSED IN INVESTIGATOR-INITIATED STUDY OF INTRATUMORAL MITAZALIMAB IN EARLY-STAGE BREAST CANCER

- First patient dosed in an investigator-initiated trial evaluating intratumoral mitazalimab, with or without intratumoral nivolumab
- Study evaluates how local CD40 activation affects the tumor microenvironment ahead of surgery to inform future clinical development
- Trial conducted at an Ivy League university in the United States

Lund, Sweden – 2 July 2026 – Alligator Bioscience (Nasdaq Stockholm: ATORX), a clinical-stage biotechnology company developing tumor-directed immuno-oncology antibody drugs, today announces that the first patient has been dosed in an investigator-initiated trial (IIT, [NCT07319195](#)) evaluating intratumoral administration of mitazalimab, Alligator’s lead CD40 agonist, in patients with early-stage breast cancer. The study will evaluate mitazalimab given as a single intratumoral dose, either alone or in combination with a single intratumoral dose of the PD-1 inhibitor nivolumab, prior to surgery.

While checkpoint inhibitors have improved outcomes in some breast cancer subtypes, there remains a need for more effective and better-tolerated immunotherapy approaches in others. In a [recent publication in NPJ Breast Cancer](#), Dr Zhang has demonstrated that CD40 agonists synergize with PD-1 inhibitor in preclinical breast cancer models eradicating tumors and providing long lasting tumor immunity. This IIT will explore if local CD40 activation can enhance anti-tumor immunity in resectable breast cancer, and generate translational insights to guide further randomized trials.

The primary endpoints are safety and feasibility of administering mitazalimab, with or without nivolumab, prior to surgery. Secondary and exploratory objectives include pathologic and imaging-based measures of anti-tumor activity and translational analyses intended to characterize immune activation in the tumor microenvironment.

*“We are pleased to support this investigator-initiated trial evaluating intratumoral mitazalimab in early-stage breast cancer. Breast cancer is the most common cancer in women, and the leading cause of cancer-related death. said **Søren Bregenholt, CEO of Alligator Bioscience**. As the biology and treatment of breast cancer varies significantly from that of pancreatic cancer this trial has the potential to generate valuable new translational insights that can guide future development to expand the clinical utility of mitazalimab.”*

About investigator-initiated trials

Investigator-initiated trials (IITs) are sponsored and executed by clinical investigators, with Alligator's consent, but without our direct involvement besides supplying mitazalimab, providing scientific input and ensuring certain aspects of clinical safety reporting. IITs offer the opportunity to strengthen our understanding of mitazalimab's mechanism of action, expand its potential use beyond pancreatic cancer, and explore additional indications to support further development. Alligator announces the initiation of an IIT once the first patient has been dosed with mitazalimab, and shares key outcomes and milestones, but does not commit to provide regular updates on individual trials.

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The information was submitted for publication, through the agency of the contact person set out above, at 10:30 a.m. CEST on 2 July 2026.

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 ready for Phase 3 development, and has previously presented unprecedented survival data at 30-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 announces first patient dosed in investigator-initiated study of intratumoral mitazalimab in early-stage breast cancer](#)