

ALLIGATOR ANNOUNCES PUBLICATION OF OPTIMIZE-1 BIOMARKER ANALYSIS IN CELL REPORTS MEDICINE SUPPORTING MITAZALIMAB AND MFOLFIRINOX IN METASTATIC PANCREATIC CANCER

Lund, Sweden – 8 October 2025 – Alligator Bioscience (Nasdaq Stockholm: ATORX), a clinical-stage biotechnology company developing tumor-directed immuno-oncology antibody drugs, today announced the publication of a peer-reviewed article in *Cell Reports Medicine*, a Cell Press journal. The paper presents biomarkers associated with clinical efficacy endpoints from the Phase 1b/2 OPTIMIZE-1 trial evaluating Alligator's CD40 agonist mitazalimab in combination with mFOLFIRINOX chemotherapy in patients with untreated metastatic pancreatic ductal adenocarcinoma (mPDAC).

The publication, titled *"CD40 agonist mitazalimab with mFOLFIRINOX in untreated metastatic pancreatic cancer: biomarkers associated with outcomes from OPTIMIZE-1"*, provides mechanistic insights into determinants of clinical response and offers translational support for a planned randomized Phase 3 trial.

Key findings from the publication include:

- **Clinical efficacy:** The OPTIMIZE-1 study met its primary endpoint, with a confirmed objective response rate of 42.1% in the Phase 2 cohort. Median duration of response was 12.6 months, progression-free survival 7.7 months, and overall survival 14.9 months. The survival rate at 24 months was 29.4%, triple that of chemotherapy alone.
- **Tumor gene signature linked to outcome:** Baseline expression of a tumor-intrinsic fibrotic gene signature, directly linked to the mode of action of mitazalimab, was associated with improved overall survival.
- **Peripheral immune activation:** Mitazalimab-induced increases in circulating activated immune cells correlated with better clinical outcomes.
- **Intratumoral immune activation:** Patients with objective clinical responses displayed mitazalimab-induced immune activation supporting mitazalimab's contribution to clinical outcomes
- **Translational impact:** strongly supports mitazalimab's contribution to the improved clinical outcomes observed in OPTIMIZE-1 and supports future development of predictive biomarkers for mitazalimab.

*"These data provide important guidance for understanding which patients may benefit most from mitazalimab-based immunotherapy in pancreatic cancer, and provides further evidence for mitazalimab's contribution to the sustained clinical benefit observed in the OPTIMIZE-1 trial" said **Søren Bregenholt, CEO of Alligator Bioscience**. "The integration of biomarker-driven insights into our clinical development strategy strengthens the foundation for the next phase of mitazalimab's evaluation in this high-need indication."*

The full article is available online through [>>this link<<](#).

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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 8 October 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 ready 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.

PRESS RELEASE

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Attachments

Alligator announces publication of OPTIMIZE-1 biomarker analysis in Cell Reports Medicine supporting mitazalimab and mFOLFIRINOX in metastatic pancreatic cancer