

## ALLIGATOR BIOSCIENCE ANNOUNCES CONTINUED ENCOURAGING OVERALL SURVIVAL BENEFIT FOR MITAZALIMAB

- Results show a 24-month survival rate of 29.4% for mitazalimab in combination with mFOLFIRINOX, triple that of chemotherapy alone
- Topline data from the 450 µg/kg cohort, further strengthens the rationale for 900 µg/kg as the Phase 3 dose
- Together the results reinforce mitazalimab's potential as a durable treatment option for metastatic pancreatic cancer

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today reports updated results from the Phase 2 OPTIMIZE-1 study evaluating mitazalimab in combination with standard chemotherapy (mFOLFIRINOX) as a first-line treatment for metastatic pancreatic cancer. The 24-month analysis of the 900 µg/kg dose reconfirms and extends the significant survival benefit and reinforces the potential of mitazalimab as a breakthrough immunotherapy candidate in this challenging disease.

The data demonstrated a 24-month survival rate of 29.4% in patients treated with mitazalimab in combination with mFOLFIRINOX. These numbers compare well to estimates of 24-month survival rates of 8% for FOLFIRINOX alone, and 20% for NALIRIFOX alone<sup>1,2</sup>.

Median follow-up duration for the 24-month analysis was 25.4 months, indicating the maturity of these outcomes. At the time of analysis, a total of 16 (28%) patients were still alive, and of these, 5 (9%) were still on treatment. The longest ongoing treatment duration was 32 months.

Median Overall Survival (mOS) in the study was 14.9 months, comparing favourably to the 11.1 months demonstrated by FOLFIRINOX<sup>1</sup> and more recently by NALIRIFOX<sup>2</sup>. The duration of response was confirmed at 12.6 months, as compared to 5.9 and 7.3 months reported for standard of care<sup>1,2</sup>.

Hence, the results show that patients responding to mitazalimab in combination with mFOLFIRINOX continue to show stable and encouraging survival outcomes over time. This highlights the consistency of mitazalimab's therapeutic effect and underscores the durable efficacy of mitazalimab when paired with standard treatment.

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In addition, the analysis provided top-line 6-month follow-up data from the 450 µg /kg dose cohort conducted to meet FDA's request for further dose characterization prior to advancing mitazalimab into Phase 3. This data showed an objective response rate of 22.7% (unconfirmed), compared to 54.4% for the 900 µg/kg dose. These findings indicate a dose-response relationship for mitazalimab and support the selection of 900 µg/kg as recommended Phase 3 dose.

*"These 24-month data further validate mitazalimab's potential to meaningfully impact treatment outcomes for pancreatic cancer patients, and the continued survival and response duration observed in the study reinforce our confidence in mitazalimab's clinical promise and its potential to reshape the treatment landscape for this aggressive disease" said **Søren Bregenholt, CEO of Alligator Bioscience**. "Moreover the 450 µg/kg topline data suggest a positive dose-response correlation, further strengthening the rationale for developing mitazalimab at the 900 µg/kg dose."*

Based on these results and a confirmed regulatory path, Alligator Bioscience remains on track in advancing mitazalimab toward confirmatory clinical trials. With mitazalimab demonstrating strong clinical efficacy, durability of response, and a clear regulatory pathway forward, Alligator Bioscience continues to actively explore strategic collaborations to accelerate late-stage development and maximize the potential of mitazalimab as a transformative treatment option for pancreatic cancer.

[1] Conroy et al., N Engl J Med 2011; 364:1817-1825; DOI: 10.1056/NEJMoa1011923

[2] Wainberg et al., Lancet 2023; 402(10409):1272-1281; DOI: 10.1016/S0140-6736(23)01366-1

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## **About Alligator Bioscience**

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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 18-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](https://alligatorbioscience.com).

## **Attachments**

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**Alligator Bioscience Announces Continued Encouraging Overall Survival Benefit for Mitazalimab**