

ALLIGATOR BIOSCIENCE REPORTS INCREMENTAL OVERALL SURVIVAL BENEFIT OF MITAZALIMAB COMBINED WITH MFOLFIRINOX BASED ON LITERATURE-BASED INDIRECT COMPARISON OF OUTCOMES

- Indirect Comparison shows significant improvement of OS of mitazalimab + mFOLFIRINOX, compared to known FOLFIRINOX and NALIRIFOX outcomes
- The data substantiates the potential of this regimen in the context of the upcoming randomized Phase 3 trial

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces positive outcomes from adjusted indirect treatment comparison studies, demonstrating that mitazalimab + mFOLFIRINOX shows significantly better Overall Survival (OS) compared to FOLFIRINOX-based and NALIRIFOX treatment regimens for the frontline treatment of metastatic pancreatic adenocarcinoma cancer (mPDAC). As the OPTIMIZE-1 trial for mitazalimab did not include a control group, these indirect treatment comparisons are a means to establish the relative efficacy of mitazalimab in combination with mFOLFIRINOX compared to existing treatment regimens.

A robust comparison was achieved using published literature from randomized Phase 2/3 studies in frontline mPDAC with mitazalimab + mFOLFIRINOX (18-month follow-up analysis), FOLFIRINOX, mFOLFIRINOX and NALIRIFOX regimens, after applying the ITC methodologies. The results demonstrated a significantly better Overall Survival (OS) potential for mitazalimab in combination with mFOLFIRINOX compared to FOLFIRINOX-based regimens (hazard ratio 0.64, 95% CI 0.46 – 0.87) and FOLFIRINOX-based plus NALIRIFOX regimens (hazard ratio 0.68, 95% CI 0.47 – 0.99). This outcome will not only inform preparation of the mitazalimab Phase 3 trial but is also valuable in the context of mitazalimab confirmatory development from both a regulatory and partnering standpoint.

These analyses were conducted by an independent clinical research organization in collaboration with expert pancreatic cancer clinicians and results were presented on January 24 at the 2025 ASCO Gastrointestinal (GI) Cancers Symposium in San Francisco, California by Professor Eileen O’Reilly in a presentation titled *“Evaluating the relative treatment efficacy of CD40 agonist mitazalimab in combination with mFOLFIRINOX in patients with metastatic pancreatic ductal adenocarcinoma (mPDAC) using unanchored indirect treatment comparisons (ITCs)”*.

*“These results further underscore the consistently positive clinical data delivered by mitazalimab, reaffirming its potential to transform the treatment landscape for metastatic pancreatic cancer,” said **Søren Bregenholt, CEO of Alligator Bioscience.** “It is yet another milestone in mitazalimab’s development, as we prepare to advance into the Phase 3 trial and continue our mission to bring innovative therapies to patients with urgent unmet needs. We eagerly anticipate the 24-month follow-up data, expected later this quarter, which will further inform the potential of mitazalimab in this critical patient population.”*

*“ITC is an acknowledged methodology in the context of health outcomes research, and particularly relevant for a disease like pancreatic cancer with short overall survival” said **Dr. Zev Wainberg, Professor of Medicine at University of California, Los Angeles (UCLA) and co-director of the UCLA Gastrointestinal (GI) Oncology Program.** “The improvement in survival indicated by these results substantiate the potential for mitazalimab combined with chemotherapy as a frontline therapy, to be evaluated in the upcoming phase 3 study.”*

The encouraging survival benefits demonstrated through this analysis contribute to the growing body of evidence supporting mitazalimab's potential in treating metastatic pancreatic cancer. These findings provide further momentum as Alligator works toward refining standards of care and improving outcomes for patients facing this devastating disease.

About the methodology

By leveraging the published data from randomized Phase 2/3 studies and applying robust indirect treatment comparison methodologies, valuable insights can be gained to support both clinical and regulatory decisions.

Matching-adjusted indirect comparison (MAIC) and simulated treatment comparison (STC) adjust for observed heterogeneity of potential effect modifiers across the study populations by utilising propensity score weighting methods and regression methods, respectively. Age, gender, presence of liver metastases and the ECOG performance status were adjusted using these standard methods. These methods, commonly referred to as indirect treatment comparison (ITC), are standard in the context of health outcomes research, and pricing & reimbursement considerations.

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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 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.

Attachments

Alligator Bioscience Reports Incremental Overall Survival Benefit of mitazalimab combined with mFOLFIRINOX based on Literature-based Indirect Comparison of Outcomes