

ALLIGATOR BIOSCIENCE ANNOUNCES INITIATION OF AN INVESTIGATOR-INITIATED INITIATION OF PHASE 1 CLINICAL STUDY OF INTRATUMORAL MITAZALIMAB IN LOCALLY ADVANCED PANCREATIC CANCER

- Study conducted by Moores Cancer Center at University of California San Diego to evaluate safety and efficacy of mitazalimab injected intratumorally at the time of surgical irreversible electroporation (IRE)
- Preclinical data suggest combination of IRE with CD40 agonism can generate systemic anti-tumor effects
- Mitazalimab demonstrated significant survival benefit in combination with mFOLFIRINOX over standard of care in OPTIMIZE-1 Phase 2 study in first-line metastatic pancreatic cancer

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces the initiation of an investigator initiated Phase 1 clinical study ([NCT06205849](#)) evaluating the safety and efficacy of the company's lead asset mitazalimab (CD40 mAb agonist) injected intratumorally at the time of surgical irreversible electroporation (IRE) in patients with locally advanced pancreatic cancer (LAPC).

The NCI-funded Phase 1a/1b single-center study will enroll up to 18 patients, who will receive a single intratumoral injection of mitazalimab immediately after the surgical IRE, a form of non-thermal ablation that is currently in clinical use for selected patients with LAPC. The study is being conducted by **researchers at Moores Cancer Center** at UC San Diego. Alligator will supply mitazalimab for the study.

"The preclinical data generated in our lab shows that the combination of IRE with an antibody that stimulates the CD40 receptor improves the response to IRE and inhibits metastatic tumor growth," said **Rebekah White, MD, principal investigator of Phase 1 of the study and associate professor of Surgery at UC San Diego School of Medicine**. *"While IRE is widely used in patients with LAPC, most will ultimately develop distant metastases. We believe that local delivery of mitazalimab at the time of IRE in patients with LAPC will be safe, augment the immune effects of IRE and decrease the risk of recurrence."*

PRESS RELEASE

14 May 2024 08:00:00 CEST



*"Intratumoral delivery of immunotherapy is gaining increased importance, and in the setting of localized disease provides an opportunity to efficiently activate the immune cells in the tumor microenvironment. In this investigator-initiated study, we are looking forward to evaluating the combination of mitazalimab administered directly into the tumor alongside IRE," said **Sumeet Ambarkhane, CMO of Alligator Bioscience**. "The strong clinical data generated by mitazalimab over the last 12 months have received a great amount of interest from the scientific and medical communities. We are very pleased that an accomplished center of clinical excellence, such as Moores Cancer Center, is conducting this study, which could broaden the clinical applicability of mitazalimab in pancreatic cancer patients."*

In January 2024, **Alligator announced positive top-line results from the OPTIMIZE-1 Phase 2 study** evaluating mitazalimab in combination with mFOLFIRINOX in 1st line metastatic pancreatic cancer. The study met its primary endpoint and also demonstrated a median Overall Survival (mOS) of 14.3 months, compared to 11.1 months for standard of care, along with an unprecedented Duration of Response of 12.5 months, compared to 5.9 months with FOLFIRINOX alone.[1]

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

For further information, please contact:

Søren Bregenholt, CEO

E-mail: soren.bregenholt@alligatorbioscience.com

Phone: +46 (0) 46 540 82 00

LifeSci Advisors

Investor Relations

Guillaume van Renterghem

E-mail: gvanrenterghem@lifesciadvisors.com

Phone: +41 (0) 76 735 01 31

The information was submitted for publication, through the agency of the contact person set out above, at 8:00 a.m. CEST on May 14, 2024.

PRESS RELEASE
14 May 2024 08:00:00 CEST



About Alligator Bioscience

Alligator Bioscience AB is a clinical-stage biotechnology company developing tumor-directed immuno-oncology antibody drugs. Alligator's portfolio includes several promising drug candidates, with the CD40 agonist mitazalimab as its key asset. Furthermore, Alligator is co-developing ALG.APV-527 with Aptevo Therapeutics Inc., several undisclosed molecules based on its proprietary technology platform, Neo-X-Prime®, and novel drug candidates based on the RUBY® bispecific platform with Orion Corporation. Out-licensed programs include AC101/HLX22, in Phase 2 development, by Shanghai Henlius Biotech Inc. and an undisclosed target to Biotheus Inc.

Alligator Bioscience's shares are listed on Nasdaq Stockholm (ATORX) and is headquartered in Lund, Sweden.

For more information, please visit alligatorbioscience.com.

Attachments

Alligator Bioscience Announces Initiation of an Investigator-Initiated Initiation of Phase 1 Clinical Study of Intratumoral Mitazalimab in Locally Advanced Pancreatic Cancer