

ALLIGATOR BIOSCIENCE & AMPHERA ANNOUNCE LAST PATIENT TREATED IN MITAZALIMAB- MESOPHER REACTIVE-2 PHASE 1 STUDY IN PANCREATIC CANCER

- REACTIVE-2 is assessing the safety and immunological effect of mitazalimab in combination with MesoPher in metastatic pancreatic cancer
- Mitazalimab and MesoPher have both achieved positive results in separate Phase 2 clinical studies in pancreatic cancer
- Preliminary results of REACTIVE-2 are expected in Q4 2023

Lund, Sweden, and 's-Hertogenbosch, the Netherlands – Alligator Bioscience AB ("Alligator") (Nasdaq Stockholm: ATORX) and Amphera B.V. ("Amphera") today announce the successful dosing of the last patient in the REACTIVE-2 Phase 1 trial evaluating mitazalimab in combination with MesoPher in patients with metastatic pancreatic cancer.

The open-label, single-center Phase 1 dose finding study is assessing the safety and efficacy of Alligator's lead asset mitazalimab (agonistic CD40 mAb), in combination with Amphera's cancer vaccine MesoPher, in patients with metastatic pancreatic cancer after standard of care treatment with mFOLFIRINOX ([NCT05650918](#)). REACTIVE-2 is an investigator-sponsored trial being performed at Erasmus Medical Center in Rotterdam. Preliminary results are expected in Q4 2023.

*"We are very pleased to have successfully reached this important milestone in the REACTIVE-2 trial." said **Rob Meijer, CEO of Amphera**. "MesoPher is able to invigorate the immune system without toxicity to the patient. This makes MesoPher ideally suited in combination treatments for difficult to treat cancer indications."*

*"Our CD40 agonist and Amphera's cancer vaccine have both shown great promise in their own separate clinical studies emphasizing the crucial role of dendritic cells and other myeloid cells in immune response to pancreatic cancer," said **Søren Bregenholt, CEO of Alligator Bioscience**. "We have high hopes that a combination of mitazalimab and MesoPher can drive clinically meaningful anti-tumor immunity and potentially offer a new therapeutic option in this hard to treat patient population."*

PRESS RELEASE

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Mitazalimab is being evaluated in combination with mFOLFIRINOX in OPTIMIZE-1, a Phase 2 trial in previously untreated patients with metastatic pancreatic cancer. In January 2023, **Alligator announced strong interim results from OPTIMIZE-1**, which demonstrated an objective response rate (ORR) of 52% in 23 evaluable patients (versus a reference ORR of around 32% in a similar patient population treated with standard of care FOLFIRINOX[1]).

MesoPher, which is comprised of autologous dendritic cells loaded with allogeneic tumor lysate (PheraLys), is being evaluated in the Phase 2 REACTIVE trial in patients with resected pancreatic cancer. In December 2022, **Amphera announced topline results from this** trial, in which MesoPher exceeded expectations, demonstrating a statistically significant 2-year Recurrence Free Survival of 60% and an excellent safety profile.

REACTIVE-2 is supported by strong preclinical data published in the high-ranking peer-reviewed *Journal for ImmunoTherapy of Cancer*[2], which demonstrated that CD40 agonists in combination with dendritic cells loaded with allogeneic tumor lysate mediate powerful and significant anti-tumor effects in pancreatic cancer models.

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

[2] Lau SP, et al. *J Immunother Cancer* 2020; 8:e000772. doi: 10.1136/jitc-2020-000772

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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.

About Amphera

Amphera is a late-stage biotechnology company developing cell therapies to treat cancer. MesoPher is comprised of autologous dendritic cells loaded with PheraLys, a lysate of tumour cell lines. PheraLys contains a broad repertoire of tumour-associated antigens, many of which are present in pancreatic cancer and other cancers.

For more information: www.amphera.nl

Image Attachments

Amphera Logo**Attachments**

[Alligator Bioscience & Amphera Announce Last Patient Treated in mitazalimab-MesoPher REACTIVE-2 Phase 1 Study in Pancreatic Cancer](#)