

Alligator Bioscience presents positive biomarker data demonstrating proof of mechanism in mitazalimab clinical Phase I study

Lund, Sweden, September 4, 2020 – Alligator Bioscience (Nasdaq Stockholm: ATORX) announced today biomarker data from a recently performed clinical Phase I study of the drug candidate mitazalimab, its wholly owned CD40 antibody in development primarily for the treatment of pancreatic cancer. The data will be presented today at the scientific conference PEGS: The Essential Protein Engineering Summit being held virtually August 31- September 4, 2020.

“The presented biomarker data confirm the proof of mechanism and strengthen our belief in mitazalimab as a powerful therapeutic agent. The observed induction of PD-L1-genes supports that mitazalimab has a potential to make tumors more responsive to PD-1 therapy. This is a very important factor and provides an opportunity for a clear path to the market and for adding benefit to patients,” commented Per Norlén, CEO at Alligator Bioscience.

The study identified a large number of upregulated genes after treatment with mitazalimab, such as PD-L1, which supports a clinical development plan for mitazalimab in combination studies with PD-1 inhibition. Furthermore, it was demonstrated that RNA sequencing can be successfully used to discover pharmacodynamic biomarkers following CD40 activation with mitazalimab.

In addition, mitazalimab was found to activate patient-derived tumor-associated macrophages. This is relevant for the upcoming OPTIMIZE-1 Phase II study in pancreatic cancer and supports the mode of action for mitazalimab.

Next step in the development of mitazalimab is the submission of a Phase II clinical trial application (CTA) which is planned for December 2020. The study (OPTIMIZE-1) is an open-label, multi-center trial assessing the clinical efficacy of mitazalimab in combination with chemotherapy (mFolfirinox) in patients with metastatic pancreatic cancer. The OPTIMIZE study will be performed at several clinics in Europe, with planned inclusion of the first patient H1 2021.

Today at 11:30 a.m. EDT in the session *“Agonist Immunotherapy targets, priming the immune system with costimulatory agents”*, Dr Peter Ellmark, PhD, VP Discovery at Alligator Bioscience will give an oral presentation with the title *“Targeting CD40 to Unleash Dendritic Cells in Immuno-Oncology – Expanding the Tumor Specific T Cell Repertoire”*. Dr Ellmark will also act as panel moderator in the sessions *“Advances in CD137 agonists”* and *“Agonist immunotherapy targets”*. For further information, please visit <https://www.pegsummit.com/Immunotherapy-Targets>.

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The information was submitted for publication, through the agency of the contact person set out above, at 08:30 a.m. CEST on September 4, 2020.

About Mitazalimab

Mitazalimab is Alligator's most advanced immunotherapy candidate intended for the treatment of different types of cancer. It activates CD40, a receptor on the dendritic cells which allows the immune system to selectively attack the cancer.

Clinical data previously communicated from mitazalimab's Phase I development program demonstrated that mitazalimab is safe and tolerated at clinically relevant dose levels, with early signs of clinical activity identified, including a partial response in a patient with renal cell cancer and prolonged stable disease ≥ 6 months in 10 patients. There is still one patient in the Phase I study, now treated with mitazalimab for more than 30 months.

About Alligator Bioscience

Alligator Bioscience AB is a clinical-stage biotechnology company developing tumor-directed immuno-oncology antibody drugs. Alligator's pipeline includes five lead clinical and preclinical drug candidates: Mitazalimab, ATOR-1015, ATOR-1017, ALG.APV-527 (co-developed with Aptevo Therapeutics Inc.) and AC101 (in clinical development by Shanghai Henlius Biotech Inc.). Alligator's shares are listed on Nasdaq Stockholm (ATORX). The Company is headquartered in Lund, Sweden. For more information, please visit www.alligatorbioscience.com.