

ALLIGATOR BIOSCIENCE AND APTEVO THERAPEUTICS ANNOUNCE POSITIVE INTERIM DATA OF DOSE ESCALATION PHASE OF ALG.APV-527 PHASE 1 STUDY IN SOLID TUMOR CANCERS EXPRESSING TUMOR ANTIGEN 5T4

- Initial interim data show favorable drug exposure and confirm ALG.APV-527 biological activity
- Early promising signs of clinical activity in heavily pretreated patients
- Dose-escalation trial data on track for readout H2 2024

Lund, Sweden, and Seattle, Washington, March 07, 2024 - Alligator Bioscience AB ("Alligator") (Nasdaq Stockholm: ATORX) and Aptevo Therapeutics ("Aptevo") (Nasdaq: APVO) today announced positive interim data from the dose escalation phase of their Phase 1 trial evaluating ALG.APV-527 for the treatment of solid tumors likely to express the tumor antigen 5T4.

The multi-center, dose escalation trial is now more than 50% enrolled, and preliminary results include:

- Treatment was overall well-tolerated, and a maximum tolerated dose has not yet been determined, dose-escalation in higher-dose cohorts is ongoing
- ALG.APV-527 could be measured in all patients with plasma concentration of ALG.APV-527 consistent with the administered dose
- Biomarker analyses indicate the expression of the targets (4-1BB and 5T4) in tumor biopsies and confirm biological activity of ALG.APV-527

Of particular interest, signs of clinical activity were observed for both enrolled patients with heavily pre-treated breast cancer. These patients demonstrated measurable level of drug in circulation (pharmacokinetics) and reproducible elevation of serum pharmacodynamic markers with dosing, suggesting the drug is biologically active. One patient remained on study for seven months and a second remains on study beyond nine months. Both patients achieved best overall response of stable disease.

"I am pleased to share that we are now dosing cohort four, heading into higher dose ranges where we believe there is potential for increased signs of clinical activity based on preclinical models. We have treated patients with multiple tumor types including breast, pancreatic, non-small cell lung cancer and colorectal cancer. It is our belief that continued analysis of this cross section of tumor types will offer important insights about ALG.APV-527 that can be used to

*increase our success in later stage development," **said Dirk Huebner, MD, Chief Medical Officer at Aptevo.** "Additionally, as the trial has progressed, we have seen growing enthusiasm among our clinical sites, evidenced by a long and growing waiting list of patients who would like to participate in the study. We look forward to announcing additional data later in the year."*

*"We're thrilled to share positive interim Phase 1 data from our trial with ALG.APV-527, a testament to our dedicated collaboration with Aptevo. The presence of both targets in tumor biopsies is a particularly encouraging finding, which underlines the potential of our novel bispecific antibody to treat multiple indications," **said Sumeet Ambarkhane, MD, CMO at Alligator Bioscience.** "We very much look forward to continuing this journey together, to make a meaningful impact in the fight against cancer."*

About the Trial

The ALG.APV-527 Phase 1 trial is a multi-center, multi-cohort, open-label trial that will include six cohorts (dose levels) in a 3+3 design*. The trial will be conducted at up to 10 sites in the U.S. among adult patients with multiple solid tumor types /histologies likely to express the 5T4 antigen. ALG.APV-527 will be given intravenously once every two weeks. The trial will assess the safety and tolerability, pharmacokinetics, pharmacodynamics and preliminary anti-tumor activity of ALG. APV-527.

*The 3+3 design proceeds in cohorts of three patients treated at increasing dose levels. Dose escalation stops when at least two out of three or six patients experience dose limiting toxicities (DLTs) at that dose level.

About ALG.APV-527

ALG.APV-527 is a bispecific conditional 4-1BB agonist, only active upon simultaneous binding to 4-1BB and 5T4. This has the potential to be clinically important because 4-1BB can stimulate the immune cells (antitumor-specific T cells and NK cells) involved in tumor control, making 4-1BB a particularly compelling target for cancer immunotherapy. 5T4 is an oncofetal tumor associated antigen overexpressed on numerous solid tumors including non-small-cell lung carcinoma (NSCLC), breast, head and neck, cervical, renal, gastric, and colorectal cancer.

Preclinical studies, highlighting the differentiated design of the molecule that minimizes systemic immune activation, allowing for highly efficacious tumor-specific responses as demonstrated by potent activity in preclinical models, were recently published in the peer-reviewed publication, *Molecular Cancer Therapeutics*, a journal of the American Association for Cancer Research (AACR).

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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 Aptevo Therapeutics

Aptevo Therapeutics Inc. is a clinical-stage biotechnology company focused on developing novel bispecific immunotherapies for the treatment of cancer. Aptevo is seeking to improve treatment outcomes and transform the lives of cancer patients. For more information, please visit www.aptevotherapeutics.com.

Safe Harbor Statement

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This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including, without limitation, Aptevo's expectations about the activity, efficacy, safety and tolerability of its therapeutic candidates and potential use of any such candidates as therapeutics for treatment of disease, whether preclinical studies will be indicative of later stage studies or clinical trials, whether biomarker analyses will continue to confirm biological activity of ALG.APV-527, whether higher dose ranges will result in increased signs of clinical activity, whether further study of ALG.APV-527 across a cross section of multiple tumor types will continue to show clinical benefit, whether Aptevo's final trial results will vary from its preliminary or interim assessments, the possibility and timing of preliminary or interim data readouts for ALG.APV-527, statements related to the progress of and enthusiasm for Aptevo's clinical programs, its expectations regarding the effectiveness of its ADAPTIR and ADAPTIR-FLEX platforms, and any other statements containing the words "may," "continue to," "believes," "expects," "optimism," "potential," "designed," "promising," "plans," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based on Aptevo's current intentions, beliefs, and expectations regarding future events. Aptevo cannot guarantee that any forward-looking statement will be accurate. Investors should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from Aptevo's expectations. Investors are, therefore, cautioned not to place undue reliance on any forward-looking statement.

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There are several important factors that could cause Aptevo's actual results to differ materially from those indicated by such forward-looking statements, including a deterioration in Aptevo's business or prospects; further assessment of preliminary data or different results from later clinical trials; adverse events and unanticipated problems, adverse developments in clinical development, including unexpected safety issues observed during a clinical trial; and changes in regulatory, social, macroeconomic and political conditions. For instance, actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including the uncertainties inherent in the results of preliminary data and preclinical studies being predictive of the results of later-stage clinical trials, initiation, enrollment and maintenance of patients, and the completion of clinical trials, the availability and timing of data from ongoing clinical trials, expectations for the timing and steps required in the regulatory review process, expectations for regulatory approvals, the impact of competitive products, our ability to enter into agreements with strategic partners or raise funds on acceptable terms or at all and other matters that could affect the availability or commercial potential of Aptevo's product candidates, business or economic disruptions due to catastrophes or other events, including natural disasters or public health crises such as the coronavirus (referred to as COVID-19), geopolitical risks, including the current war between Russia and Ukraine and the rising conflict in the Middle East, and macroeconomic conditions such as economic uncertainty, rising inflation and interest rates, increased market volatility and decreased consumer confidence. These risks are not exhaustive, Aptevo faces known and unknown risks. Additional risks and factors that may affect results are set forth in Aptevo's filings with the Securities and Exchange Commission, including its Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and its subsequent reports on Form 10-Q and current reports on Form 8-K. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Aptevo's expectations in any forward-looking statement. Any forward-looking statement speaks only as of the date of this press release, and, except as required by law, Aptevo does not assume any obligation to update any forward-looking statement to reflect new information, events, or circumstances.

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Image Attachments

[Aptevo Logo](#)

Attachments

Alligator Bioscience and Aptevo Therapeutics Announce Positive Interim Data of Dose Escalation Phase of ALG.APV-527 Phase 1 Study in Solid Tumor Cancers Expressing Tumor Antigen 5T4