

## **FIRST-IN-CLASS BISPECIFIC ANTIBODY, ALG.APV-527, MEETS IMPORTANT TRIAL ENDPOINTS IN PHASE 1 SOLID TUMOR TRIAL**

**Alligator Bioscience and Aptevo Therapeutics report favorable safety, tolerability and evidence of biological activity of ALG.APV-527, more than half of evaluable patients achieved stable disease.**

- Colon cancer patient achieved stable disease and remained on study for more than six months, breast cancer patient remained on study for more than 11 months
- Biomarker analysis confirms immune activation in the tumor microenvironment
- Data Presented at Society for Immunotherapy of Cancer on November 8, 2024

**LUND, SWEDEN and SEATTLE WA November 11, 2024, Alligator Bioscience AB ("Alligator") (ATORX) and Aptevo Therapeutics ("Aptevo") (Nasdaq: APVO)** today announced preliminary data from the companies' Phase 1 trial evaluating the first-in-class bispecific antibody, ALG.APV-527, as monotherapy for the treatment of multiple solid tumor types likely to express tumor antigen 5T4. These data indicate that trial endpoints of adequate exposure, safety, tolerability and biological activity were met. Outcomes were presented at a poster session on Friday, November 8, 2024, at the Society for Immunotherapy of Cancer Conference in Houston, Texas.

"The interim results from Phase 1 trials of ALG.APV-527 are showing encouraging outcomes, particularly in terms of safety and disease stability in the trial patients who were refractory to multiple previous therapies. Among evaluable patients, 56% (9/16) achieved stable disease in this monotherapy trial. A colon cancer patient remained on study with stable disease for more than six months as well as a breast cancer patient who remained stable for over 11 months. Importantly, there were no instances of serious liver toxicity, a notable outcome given the relatively high incidence of this side effect associated with other treatments targeting 4-1BB. By leveraging a novel bispecific approach, ALG.APV-527 aims to enhance anti-tumor immunity while avoiding the systemic toxicities that previously have hampered the 4-1BB immune receptor pathway. These findings underscore the drug's potential as a viable option for patients with solid tumors," noted Dr. Thomas Marron, MD, PhD, Professor of Immunology & Immunotherapy and Hematology/Oncology at the Icahn School of Medicine at Mount Sinai, and a leading investigator in the trial.

## **Clinical Highlights**

### ***Safety and Tolerability***

- ALG.APV-527 demonstrated positive safety and tolerability across all cohorts
- No serious liver toxicity, a common side effect of other 4-1BB targeting treatments that can cause patients to discontinue dosing, was observed
- A maximum tolerated dose has not been identified, highlighting the tolerability of the drug at high dose levels

### ***Clinical Activity/Efficacy***

- Nine of 16 efficacy evaluable patients (56%) achieved stable disease (SD)
  - One colon cancer patient achieved SD for more than six months
  - The longest SD duration was in a breast cancer patient who entered the study with progressive disease, achieved stable disease and remained on study for >11 months. This patient successfully transitioned to a higher dose level twice

### ***Evidence of biological activity of ALG.APV-527***

- ALG.APV-527 could be measured in all patients. Serum concentrations of ALG.APV-527 were proportional to the administered dose
- Analysis of biomarkers in the serum of treated patients including soluble 4-1BB (surface protein found on certain immune cells) confirm biological activity of ALG.APV-527
- Analysis of biomarkers in biopsies (including the 5T4 target cells and CD8 T cancer killer cells are consistent with immune activation in the tumor microenvironment). This observation consistent with ALG.APV-527 expected MOA.

### **About the Trial**

The ALG.APV-527 Phase 1 trial is a multi-center, multi-cohort, open-label dose-escalation trial that includes administration of ALG.APV-527 in up to six escalating dose levels in a 3+3 design\*. The trial is enrolling 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 is assessing 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.

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**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, has been published in the peer-reviewed publication, *Molecular Cancer Therapeutics*, a journal of the American Association for Cancer Research (AACR).

**About Alligator Bioscience**

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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](https://alligatorbioscience.com).

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## **About Aptevo Therapeutics**

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Aptevo Therapeutics Inc. (Nasdaq: APVO) is a clinical-stage biotechnology company focused on developing novel bispecific immunotherapies for the treatment of cancer. The company has two clinical candidates. Mipletamig is currently being evaluated in RAINIER, a Phase 1b/2 trial for the treatment of frontline acute myeloid leukemia in combination with standard-of-care venetoclax + azacitidine. Mipletamig has received orphan drug designation ("orphan status") for AML according to the Orphan Drug Act. ALG.APV-527, a bispecific conditional 4-1BB agonist, only active upon simultaneous binding to 4-1BB and 5T4, is being co-developed with Alligator Bioscience and is being evaluated in a Phase 1 clinical trial for the treatment of multiple solid tumor types likely to express 5T4. The Company has three pre-clinical candidates with different mechanisms of action designed to target a range of solid tumors. All pipeline candidates were created from two proprietary platforms, ADAPTIR® and ADAPTIR-FLEX®. The Aptevo mission is to improve treatment outcomes and transform the lives of cancer patients. For more information, please visit [www.aptevotherapeutics.com](http://www.aptevotherapeutics.com).

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**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 war between Israel and Hamas, 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.

**Attachments**

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**First-in-Class Bispecific Antibody, ALG.APV-527, Meets Important Trial Endpoints in Phase 1 Solid Tumor Trial**