

June 15, 2026



# Aptose Presents Safety, Response, and MRD Clinical Data from TUSCANY Phase 1/2 Clinical Trial of Tuspentinib Triplet Therapy in Newly Diagnosed AML at the 2026 EHA Congress in Oral Presentation

- *Addition of TUS to standard of care VEN+AZA creates a well-tolerated and mutation agnostic frontline triple drug therapy for newly diagnosed AML*
- *32 AML patients dosed across 40 mg, 80 mg, 120 mg and 160 mg TUS with TUS+VEN+AZA triplet*
- *Composite complete response (CRc) rate in evaluable patients across all dosing groups was 86.2%*
- *MRD-negativity in patients who achieved a CR/CRh response was 86.4%*
- *AML patients with diverse genetics, including TP53-mutated, complex karyotypes, and unmutated FLT3, safely achieved responses and MRD negativity*

SAN DIEGO and TORONTO, June 15, 2026 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. ("Aptose" or the "Company") (TSX: APS; OTC: APTOF), a clinical-stage precision oncology company, announced that data from its Phase 1/2 TUSCANY trial in newly diagnosed AML patients treated with tuspentinib (TUS) in combination with standard of care dosing venetoclax and azacitidine (TUS+VEN+AZA triplet) was presented yesterday in an oral presentation at the European Hematology Association Congress (EHA 2026) in Stockholm, Sweden.

The TUS+VEN+AZA triplet is being developed as a mutation agnostic frontline therapy to treat large, mutationally unrestricted and diverse populations of newly diagnosed AML patients who are ineligible to receive induction chemotherapy. Nikolai Podoltsev, MD, PhD, Associate Professor Medical Oncology & Hematology, Clinical Director, Malignant Hematology, Yale School of Medicine, and an investigator in the TUSCANY study, reported updated safety and efficacy data from the 80 mg and 120 mg dose cohorts, as well as new data from the 160 mg dose of TUS in the TUS+VEN+AZA triplet.

"While there have been recent successes with targeted therapy in AML treatment, our multi-targeted approach with tuspentinib in combination is showing significant efficacy across mutations that have been historically difficult to treat, including TP53 mutations, where we thus far have achieved CRs in all of the four subjects at the highest dose cohort," said

Rafael Bejar, MD, PhD, Chief Medical Officer, Aptose. “As a safe and effective inhibitor of multiple growth factor signaling pathways, the TUS+VEN+AZA triplet is a first line combination therapy with the potential to improve outcomes in nearly all AML populations.”

The oral presentation at EHA included updated safety, complete remission, minimal residual disease (MRD) assessments, and longer duration of follow-up:

**Presentation title:** TUSCANY Study of Safety and Efficacy of Tuspentinib Plus Standard of Care Venetoclax and Azacitidine in Study Participants with Newly Diagnosed AML Ineligible for Induction Chemotherapy

**Presenter:** Nikolai Podoltsev, MD, PhD, Associate Professor (Medical Oncology & Hematology), Department of Internal Medicine; Clinical Director, Malignant Hematology, Associate Program Director, Hematology / Medical Oncology Fellowship Program, Yale School of Medicine

### Key findings:

- 32 (29 response evaluable), newly diagnosed AML patients have received the TUS+VEN+AZA combination:
  - 4 received the 40 mg dose of TUS, 12 received the 80 mg dose of TUS, 3 received the 120 mg dose of TUS, and 13 received the 160 mg dose
- The overall CRc rate across dose levels in response evaluable (29) patients was 86.2%.
  - The MRD negative rate among all patients dosed was 62.5%; MRD negative rate in CR/CRh patients was 86.2%.
- At the 160 mg TUS dose level (n=13):
  - The overall CRc rate was 76.9% (10 of 13 patients), including 8 of 11 (72.7%) with unmutated (or wildtype) FLT3
  - 100 % composite complete remission in all 4 patients with *TP53*-mutation with complex karyotype (*TP53*-mut/CK)
- Regardless of mutation status, TUS is active in newly diagnosed AML patients
  - MRD-negative responses achieved across diverse genetic populations, including adverse *TP53* mutations and CK
  - Responses continue to evolve with 19 subjects remaining on treatment, including 6 that moved on to stem cell transplantation
- TUS can be administered safely with standard-of-care dosing of VEN/AZA
  - TUS PK properties were not significantly altered by VEN, AZA, antifungals or food
  - No treatment-related deaths
  - No treatment-related adverse events of QT<sub>c</sub> prolongation, CPK elevations or differentiation syndrome

Abstracts are available on the EHA2026 website [here](#). The presentation is available on the Aptose website [here](#).

## **TUSCANY: TUS+VEN+AZA Triplet Phase 1/2 Study**

The tuspetinib-based TUS+VEN+AZA triplet therapy is being advanced in the TUSCANY Phase 1/2 clinical study with the goal of creating an improved frontline therapy for newly diagnosed AML patients that is active across diverse AML populations, durable, and well tolerated. Earlier APTIVATE trials of TUS as a single agent and in combination as TUS+VEN demonstrated favorable safety and broad activity in diverse relapsed or refractory (R/R) AML populations that went beyond the more prognostically favorable NPM1 and IDH mutant subgroups. Indeed, responses were also in R/R AML patients with highly adverse *TP53* and *RAS* mutations, and those with mutated or unmutated (wildtype) *FLT3* genes.

The TUSCANY Phase 1/2 study, being conducted at 10 leading U.S. clinical sites by elite clinical investigators, is designed to test various doses and schedules of TUS in combination with standard dosing of AZA and VEN for patients with AML who are ineligible to receive induction chemotherapy. A convenient, once daily oral agent, TUS, is being administered in 28-day cycles.

More information on the TUSCANY Phase 1/2 study can be found on [www.clinicaltrials.gov](http://www.clinicaltrials.gov) ([here](#)).

### **About Aptose**

Aptose Biosciences is a clinical-stage biotechnology company committed to developing precision medicines addressing unmet medical needs in oncology, with an initial focus on hematology. The Company's lead clinical-stage, oral kinase inhibitor tuspetinib (TUS) has demonstrated activity as a monotherapy and in combination therapy in patients with relapsed or refractory acute myeloid leukemia (AML) and is being developed as a frontline triplet therapy in newly diagnosed AML. For more information, please visit [www.aptose.com](http://www.aptose.com).

### **Forward Looking Statements**

This press release may contain forward-looking statements within the meaning of Canadian and U.S. securities laws, including, but not limited to, statements relating to the therapeutic potential and safety profile of tuspetinib (including the triplet therapy) and its clinical development, as well as statements relating to the Company's plans, objectives, expectations and intentions and other statements including words such as "continue", "expect", "intend", "will", "should", "would", "may", and other similar expressions. Such statements reflect our current views with respect to future events and are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by us are inherently subject to significant business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance or achievements described in this press release. Such factors could include, among others: our ability to obtain the capital required for research and operations and to continue as a going concern; the inherent risks in early stage drug development including demonstrating efficacy; development time/cost and the regulatory approval process; the progress of our clinical trials; our ability to find and enter into agreements with potential partners; our ability to attract and retain key personnel; changing market conditions; inability of new manufacturers to produce acceptable batches of GMP in sufficient quantities; unexpected manufacturing defects; and other risks detailed from time-

to-time in our ongoing quarterly filings, annual information forms, annual reports and annual filings with Canadian securities regulators and the United States Securities and Exchange Commission.

Should one or more of these risks or uncertainties materialize, or should the assumptions set out in the section entitled "Risk Factors" in our filings with Canadian securities regulators and the United States Securities and Exchange Commission underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this press release and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by law. We cannot assure you that such statements will prove to be accurate as actual results and future events could differ materially from those anticipated in such statements. Investors are cautioned that forward-looking statements are not guarantees of future performance and accordingly investors are cautioned not to put undue reliance on forward-looking statements due to the inherent uncertainty therein.

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