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Aptose Announces Dosing of First Patient with 120 mg of Tuspetinib in Phase 1/2 Tuscany Trial of Frontline Triple Drug Therapy after Dose Escalation Decision by Safety Review Committee

- *TUS+VEN+AZA triplet achieves complete remissions (CRs) and minimal residual disease (MRD)-negativity with favorable safety in newly diagnosed AML patients*
- *Completed 40 mg and 80 mg TUS dose cohorts; no prolonged myelosuppression or dose-limiting toxicities*
- *No dose reductions required to the standard-of-care therapy with 40 mg and 80 mg TUS dose cohorts*
- *CSRC endorsed escalation to 120 mg TUS dosing*
- *First patient dosed with 120 mg TUS triplet and enrollment continues*

SAN DIEGO and TORONTO, May 20, 2025 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (“Aptose” or the “Company”) (OTC: APTOF, TSX: APS), a clinical-stage precision oncology company developing the tuspetinib (TUS)-based triple drug frontline therapy to treat patients with newly diagnosed AML, today announced that the Cohort Safety Review Committee (CSRC) monitoring Aptose’s Phase 1/2 TUSCANY trial of tuspetinib in combination with standard of care dosing of venetoclax and azacitidine (TUS+VEN+AZA triplet) has approved escalating from 80 mg dose TUS to 120 mg dose TUS based on its favorable review of safety and efficacy data from patients in the first two cohorts of the trial. Dosing of the first subject at the 120 mg TUS dose level has commenced. The TUS+VEN+AZA triplet is being developed as a one-of-a-kind, safe and mutation agnostic frontline therapy to treat large, mutationally diverse populations of newly diagnosed AML patients who are ineligible to receive induction chemotherapy.

No significant safety concerns or dose limiting toxicities (DLTs) have been reported in the TUSCANY trial, including no prolonged myelosuppression of subjects in remission. Patients treated in the 40 mg and 80 mg dose cohorts remain on study while enrollment is open for the 120 mg dose cohort. Aptose has reported that the first two dose cohorts have demonstrated safety, CRs, and minimal residual disease (MRD) negativity across patients with diverse mutations (press release here). The Company will be presenting updated data in an oral presentation at the European Hematology Association Congress (EHA 2025), being held June 12-15, 2025, in Milan, Italy, which will include updated safety, CRs, MRD, and pharmacokinetic (PK) clinical findings and longer duration of follow up.

“Data from the first two cohorts, with a 40 mg or 80 mg dose of TUS in the TUS+VEN+AZA triplet, reveal promising clinical safety and antileukemic activity even in some of the most

difficult-to-treat AML populations," said Rafael Bejar, M.D., Ph.D., Chief Medical Officer of Aptose. "With these significant findings, our CSRC – comprised of key leaders in the development of therapeutic agents for AML – recommended we dose escalate further, and we have now opened the 120 mg dose cohort of TUS in the triplet therapy."

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 trial 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 triplet 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. Multiple U.S. sites are enrolling in the TUSCANY trial with anticipated enrollment of 18-24 patients by mid-late 2025. Data will be released as it becomes available.

More information on the TUSCANY Phase 1/2 study can be found on 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.

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, the anticipated enrollment rate in the TUSCANY trial and the timing thereof, 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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