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Aptose Reports First Quarter 2025 Results

Highlights Progress in TUSCANY Clinical Trial of Tuspentinib in AML Triple Frontline Therapy

SAN DIEGO and TORONTO, May 08, 2025 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. ("Aptose" or the "Company") (TSX: APS and OTC: APTOF), a clinical-stage precision oncology company developing a tuspentinib (TUS)-based triple drug frontline therapy to treat patients with newly diagnosed acute myeloid leukemia (AML), today announced financial results for the first quarter ended March 31, 2025, and provided a corporate update.

"Our TUSCANY clinical trial of tuspentinib in combination with venetoclax (VEN) and azacitidine (AZA) for frontline treatment of newly diagnosed acute myeloid leukemia (AML) continues to deliver robust safety and response data, with support and enthusiasm from our clinical investigators," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer of Aptose. "We recently escalated the TUS dose to 80 mg from the initial dose of 40 mg in the TUS+VEN+AZA triplet therapy. Three patients receiving the initial dose of 40 mg and three patients receiving the 80 mg dose all have achieved complete remissions (CRs*) and continue on treatment. We are especially encouraged that two patients having highly adverse TP53 mutations have achieved objective responses and remain on treatment."

Key Corporate Highlights

- **Tuspentinib Data Reported from First Two Cohorts of TUSCANY Phase 1/2 Trial -** Tuspentinib based TUS+VEN+AZA triplet therapy is being advanced in the TUSCANY Phase 1/2 trial with the goal of creating a one-of-a-kind frontline therapy for newly diagnosed AML patients that is safe and active across diverse AML populations (mutation agnostic triplet frontline therapy), including patients without FLT3 mutations (wildtype FLT3). Data from the first two cohorts, with a 40 mg or 80 mg dose of tuspentinib in the TUS+VEN+AZA combination, reveal promising clinical safety and antileukemic activity (press release [here](#)).

In the first cohort, our newly diagnosed AML patients received the initial 40 mg dose of TUS as part of the TUS+VEN+AZA combination. No safety concerns or dose limiting toxicities (DLTs) were observed. Three patients experienced rapid bone marrow blast reductions to achieve CRs; one having biallelic mutated TP53, complex karyotype (CK) chromosomal abnormalities, and wildtype FLT3; one having an IDH2 mutation wildtype FLT3; and one having FLT3-ITD and mutated NPM1. Clinical sites or central labs reported all these patients also achieved MRD-negative status. The fourth patient at the 40 mg dose of TUS, did not achieve a complete remission and discontinued the study. The first three patients continue on treatment.

In the second cohort, three newly diagnosed AML patients having diverse mutation profiles have received the 80 mg dose of TUS, as part of the TUS+VEN+AZA combination. To date,

no safety concerns or DLTs have been reported. All patients at the 80 mg dose of TUS rapidly achieved CRs; one patient with biallelic TP53 mutations and a complex karyotype and wildtype FLT3 status, a second patient having mutated DDX41 and wildtype FLT3 status, and a third patient having FLT3-ITD and NPM1 mutations. All three patients at the 80 mg dose of TUS are early in their course of treatment, are expected to achieve normal blood count recovery as their leukemia is resolved, and MRD status will be monitored as the patients move through their courses of therapy.

- **OTC Exchange** - Aptose common shares (“the Common Shares”) are now listed for trading on the OTC Markets (OTC) under the ticker “APTOF,” in addition to the Company’s continued listing on the Toronto Stock Exchange (TSX) under the symbol “APS”. This significantly expands Aptose accessibility for U.S.-based investors and enhances overall share liquidity by enabling trading through U.S. broker-dealers. Listing on the OTC Markets is part of Aptose’s strategy to align with TSX capital markets while increasing visibility and participation from the U.S. investment community. Aptose’s Common Shares were delisted from The Nasdaq Stock Market effective April 2, 2025 because of non-compliance with the Exchange’s equity requirements.

Completed and Planned Value-Creating Milestones

2025: 1H

- Reported safety and efficacy with 40mg TUS+VEN+AZA
- Reported safety and efficacy with 80mg TUS+VEN+AZA

2025: European Hematology Association (EHA)

- Report maturing data from TUS+VEN+AZA triplet study

2025: American Society of Hematology (ASH)

- Report response rate and durability of TUS+VEN+AZA triplet
- Select TUS dose for TUS+VEN+HMA triplet Ph 2/3 PIVOTAL trials
- Prepare for initiation of Ph 2/3 PIVOTAL program

FINANCIAL RESULTS OF OPERATIONS
Aptose Biosciences Inc.
Statements of Operations Data
(unaudited)
(\$ in thousands, except for share and per share data)

	Quarter ended March 31,	
	2025	2024
Expenses:		
Research and development	\$ 2,364	\$ 6,445
General and administrative	3,097	3,315
	5,461	9,760
Operating expenses		
Other (loss) income, net	(82)	120
Net loss	\$ (5,543)	\$ (9,640)

Net loss per share, basic and diluted	\$	(2.61)	\$	(22.02)
Weighted average number of common shares outstanding used in computing net loss per share, basic and diluted		2,126,287		437,750

Net loss for the quarter ended March 31, 2025 decreased by \$4.1 million to \$5.5 million, as compared to \$9.6 million for the comparable period in 2024.

Aptose Biosciences Inc.
Balance Sheet Data
(unaudited)
(\$ in thousands)

	March 31, 2025	December 31, 2024
Cash, cash equivalents and restricted cash equivalents	\$ 4,743	\$ 6,707
Working capital	651	5,053
Total assets	7,467	10,127
Long-term liabilities	8,542	10,193
Accumulated deficit	(546,510)	(540,967)
Shareholders' deficit	(7,393)	(4,543)

- Total cash, cash equivalents and restricted cash equivalents as of March 31, 2025 were \$4.7 million. Based on current operations, the Company expects that cash on hand and available capital provides the Company with sufficient resources to fund planned Company operations including research and development until the end of May 2025. The Company is proactively implementing financing and cost reduction efforts to extend its cash runway.
- As of May 1, 2025, we had 2,552,429 Common Shares issued and outstanding. In addition, there were 38,736 Common Shares issuable upon the exercise of outstanding stock options and there were 1,267,585 Common Shares issuable upon the exercise of the outstanding warrants.

RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses for the three months ended March 31, 2025 and 2024 were as follows:

(in thousands)	Quarter ended March 31, 2025	March 31, 2024
Program costs – Tuspentinib	\$ 1,479	\$ 3,923
Program costs – Luxeptinib	98	208
Program costs – APTO-253	-	22
Personnel related expenses	646	1,924
Stock-based compensation	141	328
Depreciation of equipment	-	10
Total	\$ 2,364	\$ 6,445

Research and development expenses decreased by \$4.1 million to \$2.3 million for the quarter ended March 31, 2025, as compared to \$6.4 million for the comparable period in 2024. Changes to the components of our research and development expenses presented in the table above are primarily as a result of the following events:

- Program costs for tuspentinib were \$1.5 million for the quarter ended March 31, 2025, compared with \$3.9 million for the comparable period in 2024. The lower program costs for tuspentinib in the current period are attributable to reduced activity in our APTIVATE clinical trial, reduced manufacturing activity, and related expenses.
- Program costs for luxepatinib decreased by approximately \$0.1 million primarily due to lower clinical trial and manufacturing activities.
- Program costs for APTO-253 were zero. This was due to the Company's decision to discontinue further development of APTO-253.
- Personnel-related expenses decreased by \$1.3 million due to lower headcount for research and development personnel in the current quarter.
- Stock-based compensation decreased by approximately \$0.2 million in the quarter ended March 31, 2025, primarily due stock options forfeited and/or vested in prior periods that are no longer being expensed resulting in lower expense in the current period.

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 small molecule cancer therapeutics pipeline includes products designed to provide single agent efficacy and to enhance the efficacy of other anti-cancer therapies and regimens without overlapping toxicities. The Company's lead clinical-stage compound tuspentinib (TUS), is an oral kinase inhibitor that 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 contains forward-looking statements within the meaning of Canadian and U.S. securities laws, including, but not limited to, statements regarding the Company's clinical development plans, the clinical potential, anti-cancer activity, therapeutic potential and applications and safety profile of tuspentinib, clinical trials, upcoming milestones, financing activities, expectations regarding capital available to the Company to fund planned Company operations, the Company's cash runway, use of proceeds from financings, and statements relating to the Company's plans, objectives, expectations and intentions and other statements including words such as "continue", "expect", "intend", "will", "hope", "should", "would", "may", "potential" 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; 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 and economic conditions; unexpected manufacturing defects, the evolving regulatory and political landscape and the funding of government programs and other risks detailed from time-to-time in our ongoing current reports, quarterly filings, annual information forms, annual reports and 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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