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Aptose's New "G3" Formulation of Luxeptinib Boosts Bioavailability

- *Initial modeling predicts up to 18-fold improvement in plasma steady-state exposure –*
- *Supports exploration of continuous dosing of G3 formulation –*
- *Lead clinical compound HM43239 continues to progress on schedule –*

SAN DIEGO and TORONTO, Sept. 12, 2022 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. ("Aptose" or the "Company") (NASDAQ: APTO, TSX: APS), a clinical-stage precision oncology company developing highly differentiated oral kinase inhibitors to treat hematologic malignancies, today announced the G3 formulation of luxeptinib, designed for rapid and efficient absorption, demonstrates approximately an 18-fold improvement in oral bioavailability relative to the original G1 formulation, and that Aptose plans to move forward with the development of the G3 formulation of luxeptinib to determine if it can achieve desired exposures and deliver clinical responses while continuing to demonstrate a favorable safety profile.

The original G1 formulation was found to deliver suboptimal absorption, limiting the effectiveness of luxeptinib when administered to patients with relapsed/refractory (R/R) acute myeloid leukemia (AML) and R/R B-cell malignancies during two Phase 1 a/b clinical trials.

The new G3 formulation, designed for more efficient absorption that could lead to greater accumulation and higher steady-state exposure levels, now has been tested as a single dose in 15 patients in the ongoing clinical trials. Initial computational modeling of the pharmacokinetic (PK) properties of G3 predicts that plasma steady-state exposure achieved with continuous dosing of 50 mg of G3 (every 12 hours, Q12h) is equivalent to that of 900 mg of G1 Q12h, representing up to an 18-fold improvement in bioavailability with G3.

Aptose plans to amend the protocol of its existing Phase 1 a/b clinical trial in relapsed/refractory AML patients for submission to the FDA to incorporate continuous dosing and dose escalation of G3 into the trial. Enrollment in the Phase 1 a/b study in B-cell malignancies is paused pending favorable results from continuous dosing in the AML study.

"The G3 formulation of luxeptinib has shown a significant improvement in bioavailability and the potential for greater absorption, and we are eager to move forward with continuous dosing in our AML trial," said William G. Rice, Ph.D., Chairman, President, and Chief Executive Officer of Aptose. "The original G1 formulation of luxeptinib delivered a complete remission (CR) in one AML patient that safely achieved a particularly high plasma steady-state exposure, and we are hopeful the new G3 formulation will enable patients to receive greater exposures and benefit from treatment with Lux."

“AML is a heterogeneous disease characterized by a multitude of gene mutations, making the treatment of AML quite diverse and challenging. Our lead clinical compound, HM43239, has demonstrated clinical responses in multiple genetically defined target populations of AML. We are pleased to have two well-tolerated hematology drugs with the potential to help patients in their fight against AML,” continued Dr. Rice.

About Aptose

Aptose Biosciences is a clinical-stage biotechnology company committed to developing personalized therapies 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 has two clinical-stage investigational products under development for hematologic malignancies: HM43239, an oral myeloid kinase inhibitor in an international Phase 1/2 trial in patients with relapsed or refractory acute myeloid leukemia (AML); and luxepitinib, an oral, dual lymphoid and myeloid kinase inhibitor in a Phase 1 a/b trial in patients with relapsed or refractory B-cell malignancies who have failed or are intolerant to standard therapies, and in a separate Phase 1 a/b trial in patients with relapsed or refractory AML or high-risk myelodysplastic syndrome (MDS). 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, the clinical potential and development of Luxepitinib, its “G3” formulation and safety profile and the clinical potential, development and progress of HM43239 statements regarding the potential to regain compliance with the Nasdaq minimum bid price requirement, and statements relating to the Company’s growth, 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.

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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