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Aptose Treats First Patient with Continuous Dosing of New “G3” Formulation of Luxeptinib

SAN DIEGO and TORONTO, Nov. 14, 2022 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (“Aptose”) (NASDAQ: APTO, TSX: APS), a clinical-stage company developing highly differentiated therapeutics targeting the underlying mechanisms of cancer, today announced dosing of the first patient to receive a continuous dosing regimen of the G3 formulation of luxeptinib, a potent, non-covalent oral inhibitor of BTK and FLT3, in the ongoing Phase 1a/b clinical trial in patients with relapsed or refractory (r/r) acute myeloid leukemia (AML).

The new G3 formulation thus far has been tested as a single dose in 20 patients from an ongoing Phase 1 clinical program of luxeptinib. Modeling of the pharmacokinetic (PK) properties of G3 predicts steady-state plasma exposure from continuous dosing with 50 mg of G3 (every 12 hours, Q12h) should be comparable to that of 900 mg of the original G1 formulation Q12h, representing a significant improvement in bioavailability with G3. Patients now will receive continuous dosing at the 50mg G3 Q12h dose, with the protocol allowing for further dose escalation of G3 in subsequent patients.

“We’re pleased to incorporate the new G3 formulation of luxeptinib into our clinical trial,” said William G. Rice, Ph.D., Chairman, President, and Chief Executive Officer. “Preclinically, Lux is an extraordinary molecule, eradicating tumors with the absence of toxicity, and clinically, one patient administered the original G1 formulation in the AML trial achieved exposures that enabled a complete remission (CR). We are hopeful the G3 formulation will result in greater exposures of luxeptinib and additional responses in this difficult-to-treat patient population.”

About Luxeptinib (formerly CG-806)

Luxeptinib is an oral, first-in-class FLT3 and BTK kinase inhibitor in Phase 1 a/b clinical studies for the treatment of myeloid hematologic malignancies. This small molecule demonstrates potent inhibition of wild type and all mutant forms of FLT3 (including internal tandem duplication, or ITD, and mutations of the receptor tyrosine kinase domain and gatekeeper region) and cures animals of AML in the absence of toxicity in murine leukemia models. Likewise, luxeptinib demonstrates potent, non-covalent inhibition of the wild type and Cys481Ser (C481S) mutant forms of the BTK enzyme, as well as other oncogenic kinase pathways operative in B cell malignancies, suggesting luxeptinib may be developed for various B cell malignancy patients that are resistant/refractory/intolerant to covalent or other non-covalent BTK inhibitors. Luxeptinib also inhibits NLRP3 inflammasome function in THP-1 monocytes and bone marrow-derived macrophages, suggesting potential indications in inflammatory conditions.

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 has two clinical-stage oral kinase inhibitors under development for hematologic malignancies: tuspetinib (formerly 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 Phase 1 a/b stage development for the treatment of patients with relapsed or refractory hematologic malignancies. 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 clinical development plans and potential of luxepitinib and its G3 formulation, and operations 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; inability of new manufacturers to produce acceptable batches of GMP in sufficient quantities; unexpected manufacturing defects; the potential impact of the COVID-19 pandemic and other risks detailed from time-to-time in our ongoing current reports, 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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