

Aptose Biosciences Submits IND Application for CG-806

CG-806 non-covalent pan-FLT3/pan-BTK inhibitor being developed for the treatment of chronic lymphocytic leukemia and other B cell malignancies and for acute myeloid leukemia

SAN DIEGO and TORONTO, Feb. 25, 2019 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. ("Aptose" or the "Company") (NASDAQ: APTO, TSX: APS), today announced that it has submitted an Investigational New Drug (IND) application for CG-806 to the U.S. Food and Drug Administration (FDA) requesting approval to initiate its Phase 1 clinical trial program. CG-806 is an oral, first-in-class small molecule inhibitor of all known forms of FLT3 and BTK kinases being developed for the treatment of patients with select hematologic malignancies, including chronic lymphocytic leukemia (CLL/SLL) and non-Hodgkin's lymphomas, as well as for patients with relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS).

Pending regulatory allowance, Aptose plans to conduct a Phase 1 trial with orally administered CG-806 in patients with relapsed or refractory B cell malignancies, including CLL/SLL and non-Hodgkin lymphomas (NHL) who failed or are intolerant to standard therapies. Pending the collection of predictive pharmacokinetic data in humans, Aptose would seek allowance from the FDA to move into the AML/MDS patient population in a separate Phase1 trial. The initial goal of both trials is to evaluate safety, tolerability and pharmacokinetics of CG-806 in these patient populations.

"In preclinical studies, Aptose and collaborators demonstrated that CG-806 potently inhibits all known forms of FLT3 and BTK and suppresses multiple oncogenic pathways to cripple the malignant cells and avoid rapid emergence of drug resistance, but is not a "dirty" drug that inadvertently inhibits numerous targets associated with toxicity. CG-806 delivers safety and durability of cures in animal models of cancer and readily differentiates from competitor FLT3 and BTK inhibitors," said William Rice, Ph.D., Chairman, President & CEO. "Principle investigators from across the country have voiced their eagerness to enroll patients in both clinical trials, and we hope CG-806 can serve as a new tool for clinicians to treat patients critically ill with hematologic cancers, particularly those who discontinued other BTK or FLT3 inhibitors."

About CG-806

CG-806 is an oral, first-in-class pan-FLT3/pan-BTK multi-cluster kinase inhibitor. This small molecule, in-licensed from CrystalGenomics Inc. in Seoul S. Korea, 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), cures animals of acute myeloid leukemia (AML) tumors in the absence of toxicity in murine

xenograft models, and represents a potential best-in-class therapeutic for patients with AML. Likewise, CG-806 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 CG-806 may be developed for various B cell malignancy patients (including CLL, MCL, DLBCL and others) that are resistant/refractory/intolerant to covalent BTK inhibitors. Because CG-806 targets key kinases/pathways operative in malignancies derived from the bone marrow, it is in development for B cell cancers and AML.

About Aptose Biosciences

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. APTO-253, the only known clinical stage agent that directly targets the MYC oncogene and inhibits its expression, is in a Phase 1b clinical trial for the treatment of patients with relapsed or refractory acute myeloid leukemia (AML) or high risk MDS. CG-806 is an oral, first-in-class pan-FLT3/pan-BTK multi-cluster kinase inhibitor being developed to treat AML and certain B cell malignancies. For further 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 our development plans and timelines of CG-806, potential regulatory actions, the clinical potential and favorable properties of CG-806, the clinical trials results for CG-806 and their expected timing, and 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; 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; 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.

For further information, please contact:

Aptose Biosciences

Greg Chow
Senior Vice President, CFO
650-718-5028
gchow@aptose.com

SMP Communications

Susan Pietropaolo
201-923-2049
susan@smpcommunications.com

CrystalGenomics

Steven Kim
Director, Business Development
+82-31-628-2720
skim@cgxinc.com

LifeSci Advisors, LLC

Daniel Ferry
Managing Director
617-535-7746
Daniel@lifesciadvisors.com



Source: Aptose Biosciences, Inc.