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FDA Grants Orphan Drug Designation to Aptose Biosciences for CG'806 in Acute Myeloid Leukemia

SAN DIEGO and TORONTO, Dec. 26, 2017 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (NASDAQ:APTO) (TSX:APS) today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation to CG'806, a highly potent pan-FLT3/pan-BTK inhibitor, for the treatment of patients with acute myeloid leukemia (AML).

AML is a particularly devastating cancer of the blood and bone marrow and is the most common type of acute leukemia among adults, with an annual incidence of approximately 21,000 patients and causing more than 10,000 deaths each year in the U.S.

"We are pleased that the FDA has recognized the unique potential of CG'806 to address AML and has assigned CG'806 the status of orphan drug designation," said William G. Rice, Ph.D., Chairman, President and CEO. "Results from non-clinical studies that we and our research collaborators have generated are promising and give reason for our eagerness to begin clinical trials in both AML and B-Cell malignancies in 2018."

AML cells utilize multiple forms of the FLT3 receptor tyrosine kinase and other pathways to promote rapid proliferation and to escape the inhibitory activities of many therapeutics. CG'806 is a highly potent inhibitor that simultaneously targets all known forms of FLT3 and other key oncogenic pathways that drive the proliferation of AML cancer cells, thereby providing CG'806 with a broad range of activity against AML and a strategy to delay mutational escape.

The FDA's Office of Orphan Drug Products assigns orphan drug designation to support the development of medicines for underserved patient populations, or rare disorders, that affect fewer than 200,000 people in the United States. Orphan drug designation provides Aptose certain benefits, including market exclusivity upon regulatory approval if received, exemption of FDA application fees and tax credits for qualified clinical trials.

About CG'806

CG'806 is an oral, first-in-class pan-FLT3/pan-BTK inhibitor. This small molecule demonstrates potent inhibition of all wild type and mutant forms of FLT3 tested (including internal tandem duplication, or ITD, and mutations of the receptor tyrosine kinase domain and gatekeeper region), suppresses multiple oncogenic pathways operative in AML, eliminates AML tumors in the absence of toxicity in murine xenograft models, and represents a potential best-in-class therapeutic for patients with FLT3-driven AML. Likewise, CG'806 demonstrates potent, non-covalent inhibition of the wild type and Cys481Ser mutant forms of the BTK enzyme, as well as other oncogenic kinases operative in B cell malignancies, suggesting CG'806 may also be developed for CLL and MCL patients that are

resistant/refractory/intolerant to covalent BTK inhibitors.

About Aptose

Aptose Biosciences is a clinical-stage biotechnology company committed to developing personalized therapies addressing unmet medical needs in oncology. Aptose is advancing new therapeutics focused on novel cellular targets on the leading edge of cancer. 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. For further 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 of CG'806, its clinical development, and the potential benefits that may be derived from orphan drug designation 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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