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Aptose Submits Formal Response to Clinical Hold for APTO-253

SAN DIEGO and TORONTO, Sept. 12, 2016 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (NASDAQ:APTO) (TSX:APS), a clinical-stage company developing new therapeutics and molecular diagnostics that target the underlying mechanisms of cancer, announced today that it has submitted a formal response to the U.S. Food and Drug Administration (FDA) regarding the previously announced clinical hold of Aptose's Phase 1b clinical trial of APTO-253 in patients with hematologic cancers. Aptose provided responses to all of the questions cited in the clinical hold letter issued by the FDA.

"This submission represents months of disciplined labor to resolve a manufacturing matter related to APTO-253 that arose during our Phase 1b Trial in patients with AML and high-risk MDS," commented Dr. William G. Rice, Chairman, President and Chief Executive Officer. "Although the FDA will make the ultimate decision whether our clinical trial may resume, all of their questions have been addressed."

During a Phase 1b clinical trial with APTO-253, a clinical site experienced stoppage of the infusion pump during an IV infusion caused by back pressure as a result of clogging of the in-line filter. The Company determined the root cause was a chemistry-based issue with the molecule, and the Company is now working with a drug product that does not cause filter clogging or pump stoppage during mock infusion studies performed to confirm the acceptability of the updated product through the clinical infusion procedures. Such improvements to the APTO-253 manufacturing process required to address the filter clogging event will be incorporated into a Chemistry, Manufacturing and Control (CMC) amendment to our Investigational New Drug application.

About Aptose

Aptose Biosciences is a clinical-stage biotechnology company developing personalized therapies to address unmet medical needs in oncology, with a particular focus on hematologic malignancies. Aptose is advancing new therapeutics focused on well validated and novel drug targets on the leading edge of cancer research, coupled with validated biomarkers to identify the optimal patient population for our products. The company's small molecule cancer therapeutics pipeline includes products designed for potent single agent activity and to enhance the efficacy of existing anti-cancer therapies without overlapping toxicities. Aptose Biosciences Inc. is listed on NASDAQ under the symbol APTO and on the TSX under the symbol APS. 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. Such statements include, but are not limited to, statements relating to the return of APTO-253 to the clinic and the process to have the clinical hold lifted by the

FDA 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 conditions; uncertainty in the length of the clinical hold and the conditions the FDA may impose to lift it; 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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