

October 13, 2016



## **Aptose Provides Update on FDA Clinical Hold of APTO-253**

SAN DIEGO and TORONTO, Oct. 13, 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, today announced that it received a response from the U.S. Food and Drug Administration (FDA) regarding the clinical hold of Aptose's Phase 1b clinical trial of APTO-253 in patients with hematologic cancers requesting additional information and informing Aptose that the hold would not be removed until this information is submitted and reviewed. The FDA response to Aptose focused exclusively on the request to provide the FDA with complete Chemistry, Manufacturing and Control (CMC) information on the final GMP drug substance and drug product intended for the clinic.

"Data provided to the FDA in our response to their clinical hold questions were collected using prototype batches of API and drug product. As the drug substance was changed from a salt to a free base, and thus modifying the drug product formulation, the FDA has requested additional information on the GMP-grade drug substance and drug product that is proposed for use in the clinic prior to making a decision on the hold and approval for the re-initiation of the clinical trial," commented William G. Rice, Ph.D., Chairman, President and CEO. "We continue to believe that we are on the correct path to resolve the clinical hold questions. There is an opportunity to create new intellectual property related to the new formulation of APTO-253, a drug that has demonstrated in vitro inhibition of c-Myc expression in AML cells without toxicity to normal bone marrow cells, a powerful differentiator in the treatment of AML."

The Company believes it has now developed a drug product that does not cause filter clogging or pump stoppage during simulated infusion studies. The new formulation offers the potential for improved handling characteristics for administration by infusion. Generation of the additional data requested by FDA is underway, and once available the data will be submitted for FDA review, after which time FDA will make a decision on the clinical hold. Enrollment of patients in the trial may resume only following FDA removal of the clinical hold and Investigational Review Board (IRB) approvals at the participating clinical trial sites.

### **Conference Call and Webcast**

Aptose will host a conference call on, Thursday, October 13, 2016 at 8:30 a.m. eastern time. Participants can access the conference call by dialing toll-free (844) 882-7834 (North America toll free number) or (574) 990-9707 (international toll free number), using the conference call passcode 99273697. The conference call can also be accessed at <http://edge.media-server.com/m/p/99p9qb4f> and will be available through a link on the Investor Relations section of Aptose's website at [ir.aptose.com](http://ir.aptose.com). Please log onto the webcast at least 10 minutes prior to the start of the call to ensure time for any software downloads

that may be required. An archived version of the webcast along with a transcript will be available on the company's website for 30 days.

An audio replay of the webcast will be available approximately two hours after the conclusion of the call for 7 days by dialing (855) 859-2056, using the passcode 99273697.

## **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](http://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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