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Aptose Voluntarily Suspends Clinical Dosing of APTO-253 to Review Drug Manufacturing Processes and Procedures

FDA Subsequently Institutes Clinical Hold

SAN DIEGO, California and TORONTO, Ontario, Nov. 20, 2015 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (NASDAQ:APTO) (TSX:APS) (Aptose or the Company), a clinical-stage company developing new therapeutics and molecular diagnostics that target the underlying mechanisms of cancer, today announced that the Food and Drug Administration (FDA), following a voluntary suspension of dosing by the Company and discussions with the Company, placed the Phase Ib clinical trial of APTO-253 in patients with hematologic cancers on clinical hold. This hold is intended to ensure patient safety on the trial and to ensure manufacturing and dosing procedures are consistent with the appropriate documented quality standards.

The voluntary suspension of dosing by the Company was initiated as a result of a planned preliminary review, which was accelerated to evaluate manufacturing processes and procedures upon the report of an operational difficulty with an IV infusion pump at a clinical site. The pump experienced back pressure during IV patient dosing at the point of the filter. Further review discovered preliminary concerns regarding the documentation records of the manufacturing procedures of the drug product associated with APTO-253.

The Company stated that a complete safety review of all patient files had been completed prior to initial discovery of the manufacturing documentation irregularities, and there have been no drug-related serious adverse events (SAEs) reported. The observed pharmacokinetic levels in the patients treated were within the expected range.

"We are disappointed by these events and have engaged an independent third party review. Importantly, this finding does not undermine the positive safety profile that APTO-253 has demonstrated in clinical development, and we remain confident in its potential as a promising therapeutic option for patients with acute myeloid leukemia and other hematologic malignancies," said William G. Rice, Ph.D., Chairman, President and CEO. "While we expect some delay in the clinical trial, we are committed to ensuring that upon re-initiation of clinical dosing the drug product is of the highest standards. We plan to provide updated timeline guidance as soon as practical."

Key Points:

- An internal review identified potential documentation irregularities and the Company voluntarily and immediately suspended dosing of patients out of an abundance of caution to ensure safety.

- Aptose currently possesses a sufficient supply of API to create fresh batches of drug product for the resumption of clinical dosing upon FDA approval and guidance.
- New contract manufacture organizations have been identified to manufacture fresh batches of cGMP clinical supply upon completion of investigation and in coordination with FDA guidance.
- Overall effect to the Phase Ib trial timeline is expected to be partially mitigated by initiation of the new trial sites and updated timeline will be reported as soon as determined.

About Aptose Biosciences

Aptose Biosciences is a clinical-stage biotechnology company committed to discovering and 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 research, coupled with companion diagnostics to identify the optimal patient population for our products. The Company's small molecule cancer therapeutics pipeline includes products designed to provide enhanced efficacy with existing anti-cancer therapies and regimens without overlapping toxicities. Aptose Biosciences Inc. is listed on NASDAQ under the symbol APTO and on the TSX under the symbol APS.

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 with respect to matters such as APTO-253 having potential as a promising therapeutic option; the length of delay in the Phase Ib trial timeline and the possible mitigation thereof; the sufficiency of the Company's supply of API; 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 expressed or implied forward looking statements 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; potential loss of API; inability of new manufacturers to produce acceptable batches of cGMP 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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