

Aptose Biosciences Provides Update on APTO-253 Development

SAN DIEGO and TORONTO, Dec. 29, 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 provided an update on the development of APTO-253, its investigational compound for acute myeloid leukemia (AML). The company has successfully manufactured multiple batches of a new drug product formulation for APTO-253, including a batch that has been stable and soluble for over six months. However, Aptose will have to repeat the production of the fourth batch, a 40L batch that was the intended clinical supply, because of a correctable engineering design incompatibility during the filling process. Aptose expects the batch records and release specifications from such a new batch, along with the stability and sterility data, to be provided to the FDA during the first quarter of 2017.

The need to strengthen the filling process is not a reflection on the drug substance or new formulation, both of which continue to perform favorably. Indeed, the new formulation demonstrates an increase of three times plasma drug exposure as compared to the prior formulation and may have the potential to create additional intellectual property for the company. Aptose also demonstrated that APTO-253 acts by inhibiting expression of the c-Myc oncogene without toxicity to normal bone marrow and blood cells, thereby potentially increasing the likelihood of application to additional cancer indications.

"We remain committed to the development of APTO-253, a small molecule agent that may provide benefit to an important patient population," said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. "While we have encountered delays in manufacturing activities, we also have continued mechanistic and pharmacokinetic testing of APTO-253 which heighten its viability. In parallel, we also continue to advance the development of CG'806, an exciting preclinical compound for patients with FLT3-driven AML and certain B-cell malignancies."

In November of last year, Aptose's phase 1b trial of APTO-253 was temporarily suspended because of the report of an operational difficulty with an IV infusion pump at a clinical site. The company has spent the year identifying the root cause of the clogging issue and actively evaluating multiple formulation and production methodologies in order to improve solubility and stability characteristics and select the best approach to optimizing the delivery of the product to patients with the goal of re-entering the clinic. Aptose is currently working on submitting information requested by the FDA as a result of the development of a new drug product that does not cause filter clogging or pump stoppage during simulated infusion studies.

About Aptose

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 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 contains forward-looking statements within the meaning of Canadian and U.S. securities laws, including, but not limited to, statements relating to the return of APTO-253 to the clinic, the process to respond to the continued clinical hold, the approval of the reinitiation of the trial by the FDA, the ongoing stability program for APTO-253, the manufacturing of a new batch of drug product and its submission to the FDA, the performance of the drug product and new formulation, the potential creation of new intellectual property, the potential application of APTO-253 to additional cancer indications, the viability of APTO-253, the development of CG'806 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 remove it; potential loss of API; 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, CFO 647-479-9828 gchow@aptose.com

SMP Communications
Susan Pietropaolo
O: 845-638-6290
M: 201-923-2049
susan@smpcommunications.com



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