May 4, 2022

Aptose Receives Fast Track Designation for HM43239 in Relapsed/Refractory AML Patients and FLT3 Mutation

SAN DIEGO and TORONTO, May 04, 2022 (GLOBE NEWSWIRE) -- Aptose Biosciences Inc. (“Aptose” or the “Company”) (NASDAQ: APTO, TSX: APS), a clinical-stage precision oncology company developing highly differentiated oral kinase inhibitors to treat hematologic malignancies, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to HM43239, an oral, myeloid kinome inhibitor, for the treatment of patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with FLT3 mutation. Currently, an international Phase 1/2 clinical trial is ongoing for HM43239 in the R/R AML patient population. HM43239 received orphan drug designation from the FDA for treatment of acute myeloid leukemia in 2018.

“Fast Track status acknowledges HM43239’s potential to fill an unmet need for AML patient populations and supports our efforts as we advance it towards a potential registration study,” said William G. Rice, Ph.D., Chairman, President and Chief Executive Officer. “HM43239, which potently inhibits all tested forms of FLT3 and the SYK and JAK driven pathways, already has delivered complete remissions in a broad diversity of relapsed or refractory AML patients in an ongoing Phase 1/2 clinical trial, including patients with prior failure of other FLT3 inhibitor agents. Fast Track designation will help facilitate the drug’s development.”

About Fast Track Designation

Fast Track is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. Once a drug receives Fast Track designation, early and frequent communication between the FDA and the sponsor is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading to earlier drug approval and access by patients. Visit the FDA website for more information.

About HM43239

HM43239 is a potent oral genotype-agnostic small molecule inhibitor of a constellation of kinases operative in myeloid malignancies and known to be involved in tumor proliferation, resistance to therapy, and differentiation. Currently being developed for the treatment of patients with acute myeloid leukemia (AML), HM43239 is a potent inhibitor of FLT3, SYK, mutant forms of cKIT, JAK1/2, and other kinases. Regarding FLT3, HM43239 is highly active *in vivo* against FLT3 internal tandem duplication (ITD), as well as resistance-conferring D835 and gatekeeper (F691) tyrosine kinase domain (TKD) mutations. *In vivo* murine xenograft models suggest superior antitumor activity and favorable tolerability relative to established kinase inhibitor in AML, including gilteritinib (FLT3 inhibitor) and entospletinib (SYK inhibitor).

Additionally, *in vivo* xenograft models suggest synergy with inhibitors of DNMT, BCL-2, and other key therapeutic targets, highlighting the combinatorial optionality of HM43239 in AML. In an ongoing international Phase 1/2 clinical trial, HM43239 has delivered complete remissions in a diversity of relapsed or refractory AML patients and continues to be a well-tolerated oral agent.

About Aptose

Aptose Biosciences is a clinical-stage biotechnology company committed to developing personalized therapies addressing unmet medical needs in oncology, with an initial focus on hematology. 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. The Company has two clinical-stage investigational products under development for hematologic malignancies: HM43239, an oral, myeloid kinome inhibitor in an international Phase 1/2 trial in patients with relapsed or refractory acute myeloid leukemia (AML); and luxeptinib, an oral, dual lymphoid and myeloid kinome inhibitor in a Phase 1 a/b trial in patients with relapsed or refractory B-cell malignancies who have failed or are intolerant to standard therapies, and in a separate Phase 1 a/b trial in patients with relapsed or refractory AML or high risk myelodysplastic syndrome (MDS). For more 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 regarding the clinical potential and development of HM43239 and statements relating to the Company's growth, plans, objectives, expectations and intentions and other statements including words such as "continue", "expect", "intend", "will", "hope" "should", "would", "may", "potential" 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 and economic conditions; inability of new manufacturers to produce acceptable batches of GMP in sufficient quantities; unexpected manufacturing defects; the potential impact of the COVID-19 pandemic and other risks detailed from time-to-time in our ongoing current reports, 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 Inc.
Susan Pietropaolo
Corporate Communications & Investor Relations
201-923-2049
spietropaolo@aptose.com

LifeSci Advisors, LLC
Dan Ferry, Managing Director
617-535-7746
Daniel@LifeSciAdvisors.com

Source: Aptose Biosciences, Inc.