Kronos Bio Announces Prioritization of Clinical Portfolio to Focus on Lanraplenib and KB-0742

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Company to discontinue Phase 3 entospletinib trial for strategic reasons

Enrollment continues for Phase 1/2b trial in relapsed/refractory AML with Kronos Bio's next generation SYK inhibitor, lanraplenib

Company on track to provide KB-0742 update from ongoing Phase 1/2 clinical trial in Q4

With $270.3 million in cash, cash equivalents and investments as of Sept. 30, 2022, Kronos Bio extends expected cash runway from Q4 2024 into Q2 2025

Conference call and webcast scheduled for today at 4:30 p.m. ET

SAN MATEO, Calif. and CAMBRIDGE, Mass., Nov. 08, 2022 (GLOBE NEWSWIRE) -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, today announced the prioritization of its clinical portfolio to focus on the development of its next generation SYK inhibitor, lanraplenib, and its CDK9 inhibitor, KB-0742.

The company is discontinuing the Phase 3 trial of its SYK inhibitor, entospletinib, for the treatment of newly diagnosed patients with NPM1-mutated acute myeloid leukemia (AML) and plans to close the trial to further enrollment. Patients already enrolled in the trial may complete their course of treatment. The trial is not being discontinued due to adverse events or lack of efficacy signals.

Kronos Bio decided to end the trial after its recent review of enrollment data. In this assessment, the company projected significant delays due to several factors, including the operational challenges the company faced in enrolling a genetically defined subset of patients in a front-line setting, the residual and ongoing impacts of the COVID-19 pandemic, and the inability to activate planned clinical trial sites in Russia and Ukraine.

Kronos Bio believes the most promising path forward for bringing a transformational therapy to patients for the treatment of AML is to focus the company's SYK inhibitor program on lanraplenib, initially in the relapsed/refractory setting where the need is particularly acute. The company will also continue to prioritize its investigational CDK9 inhibitor, KB-0742, which is currently in a Phase 1/2 clinical trial in patients with solid tumors, with a planned update on the trial on track for the fourth quarter.

This prioritization is expected to extend cash runway from the fourth quarter of 2024 into the second quarter of 2025.

"Focusing on lanraplenib and KB-0742 will allow us to direct our resources to the highest value programs and deliver on our mission of bringing cancer drugs to the patients with the greatest need," said Norbert Bischofberger, Ph.D., president and chief executive officer of Kronos Bio. "This is the right decision at the right time, and it makes us a stronger company as a result. I want to express my gratitude to the clinicians and the patients who participated in our entospletinib trial, as well as our employees, for their contributions to advancing potential new therapies to treat AML."

The company will also continue to invest in its platform-based discovery and development programs, as it works toward an investigational new drug application for its next pipeline candidate.

Lanraplenib Phase 1b/2 Trial: A Next-Generation SYK Inhibitor with Potential to Address Significant Unmet Need Among Patients with R/R AML

Kronos Bio remains committed to its SYK inhibitor program and to patients with AML. The company is advancing the lanraplenib program based on the strong biological rationale for the targeting of SYK in patients with genetically defined subsets of AML. This includes NPM1 and FLT3 mutations, as well as MLL rearrangement.

Lanraplenib has a number of advantages over entospletinib, including once daily dosing and the ability to be taken fed or fasted. Additionally, lanraplenib may be co-administered with proton-pump inhibitors for patients who require these medications to manage their gastro-esophageal reflux or related conditions. Lanraplenib has demonstrated favorable pharmacokinetic (PK), pharmacodynamic (PD) and safety in more than 250 trial participants, including healthy volunteers and patients with autoimmune diseases. In preclinical studies, lanraplenib was shown to have anti-leukemic activity against NPM1-mutated and FLT3-mutated patient-derived AML cells and to synergize with gilteritinib.

Kronos Bio is actively enrolling patients in the dose escalation portion of a Phase 1b/2 trial. The trial is aimed at a group of patients with low response rates to gilteritinib, the only therapy currently approved for this patient population, and generally poor prognosis. Only an estimated 10% of patients with relapsed/refractory AML survive five years from the time of relapse.

"Outcomes are poor for patients with relapsed/refractory AML and there is significant need for better treatment options," said Jorge DiMartino, M.D., Ph.D., chief medical officer and executive vice president of Clinical Development of Kronos Bio. "Beyond this first indication, lanraplenib has the potential to be a cornerstone of future targeted treatment regimens in AML and today's announcement positions us to focus our resources where the need is the greatest with the greatest possible urgency."

Lanraplenib has the potential for use in combination with a number of additional targeted agents in genetically defined subsets of AML. This includes both additional relapsed/refractory disease indications, as well as in patients with newly diagnosed AML.

The company anticipates sharing initial data from the lanraplenib/gilteritinib trial, along with the recommended Phase 2 dose (RP2D), in the fourth quarter of 2023 or first quarter of 2024.

Phase 1/2 KB-0742 Trial: Potential to Change Treatment Landscape Across Cancers

Kronos Bio remains on track to report PK, PD and safety data, as well as the recommended Phase 2 dose, from the Phase 1/2 trial of KB-0742 in the fourth quarter.

KB-0742 is a highly selective, orally bioavailable inhibitor of cyclin dependent kinase 9 (CDK9). CDK9 is a global regulator of transcription and key cofactor of many oncogenic transcription factors, including the MYC family of transcription factors. MYC is a long-recognized driver of cancer and sought-after drug target. MYC is amplified in approximately 30% of solid tumors, including those affecting the lungs, ovaries and breast.

"We remain enthusiastic about the potential of KB-0742 and will provide an update on the program during the fourth quarter," said Dr. Bischofberger. "We have seen strong preclinical evidence that demonstrates activity of KB-0742 across a number of tumor types. We look forward to sharing more about this compound before the end of the year."

After reaching RP2D, the company plans to enroll two cohorts of patients in the next stage of the trial: patients with *MYC*-amplified solid tumors and patients with transcriptionally addicted tumors.

Following the Q4 2022 update from ongoing KB-0742 trial, the company anticipates sharing initial KB-0742 efficacy data in the second half of 2023.

Conference Call

At 4:30 p.m. Eastern Time today, Kronos Bio will host a conference call to discuss this announcement. A live webcast will be available at https://ir.kronosbio.com/investor-relations and will be archived on the website following the live event.

Dial-in Information

Dial-in Number: 800-245-3047 / International: 203-518-9765
Conference ID: UPDATE22

About Kronos Bio, Inc.

Kronos Bio is a biopharmaceutical company that is advancing two investigational compounds in clinical trials for patients with cancer. The company is developing the CDK9 inhibitor, KB-0742, as a treatment for *MYC*-amplified solid tumors, and lanraplenib, a next-generation SYK inhibitor, for patients with relapsed/refractory FLT3-mutated acute myeloid leukemia. The company's scientific focus is on developing medicines that target the dysregulated transcription that is the hallmark of cancer and other serious diseases.

Kronos Bio is based in San Mateo, Calif., and has a research facility in Cambridge, Mass. For more information, visit www.kronosbio.com or follow the company on LinkedIn.

Forward-Looking Statements

Statements in this press release that are not statements of historical fact are forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. The press release, in some cases, uses terms such as "anticipate," "believes," "expect," "look forward to," "next," "on track to," "plan," "potential," "will," or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding Kronos Bio's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things, the most promising path forward for Kronos Bio's SYK inhibitor program, Kronos Bio's product development plans, the benefits of directing cash resources to specific programs in lieu of others, Kronos Bio's plan to continue to invest in its platform-based discovery and development programs, an investigational new drug application for the next pipeline candidate, the potential of lanraplenib to address a significant unmet need among patients with relapsed/refractory AML, the potential of lanraplenib to be a cornerstone of future targeted treatment regimens in AML, the potential of lanraplenib for use in combination with a number of additional targeted agents in genetically defined subsets of AML, Kronos Bio's plan to provide an update and recommended Phase 2 dose for the KB-0742 trial and the timing thereof, Kronos Bio's enrollment plans for KB-0742 after reaching recommended Phase 2 dose, Kronos Bio's plan to provide a further update and share initial efficacy data for KB-0742 and the timing thereof, Kronos Bio's expected cash runway and other statements that are not historical fact. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: Kronos Bio has encountered and may continue to encounter delays and difficulties initiating clinical trial sites and enrolling patients in its clinical trials, and, as a result, its clinical development activities could be delayed or otherwise adversely affected; Kronos Bio's approach to the discovery and development of product candidates is unproven, and it may not be successful in its efforts to use and further develop its product engine to expand its pipeline of product candidates with commercial value; Kronos Bio's discovery and development activities are primarily focused on novel cancer therapeutics for patients with genetically-defined cancers and it is difficult to predict the time and cost of developing its product candidates and obtaining regulatory approval; whether Kronos Bio will be able to progress its ongoing clinical trials on the timelines anticipated, including due to risks associated with the COVID-19 pandemic and risks inherent in the clinical development of novel therapeutics; risks related to Kronos Bio's lack of experience as a company in conducting clinical trials; the risk that results of preclinical studies and early clinical trials are not necessarily predictive of future results; Kronos Bio's projected cash runway is based on the company's current development plans and assumptions that may prove to be wrong, and changing circumstances may likewise cause the company to consume capital significantly faster than it currently anticipates; and other risks associated with the sufficiency of Kronos Bio's cash resources and need for additional capital. These and other risks are described in greater detail in Kronos Bio's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 4, 2022. Any forward-looking statements that are made in this press release speak only as of the date of this press release and are based on management's assumptions and estimates as of such date. Except as required by law, Kronos Bio assumes no obligation to update the forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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