Kronos Bio Announces Restructuring to Focus Resources on Clinical Development with Extended Cash Runway

March 7, 2024

Company to assess KB-0742 at planned new dose schedule in ongoing phase 1/2 study; topline data from expansion cohort at new dose schedule expected in the first half of 2025

IND-enabling studies for KB-9558 expected to complete in 2024 with first-in-human study anticipated to commence in 2025

Restructuring plan extends anticipated cash runway into the second half of 2026

Company to continue to focus discovery efforts on maturing projects and Genentech collaboration activities

SAN MATEO, Calif., and CAMBRIDGE, Mass., March 07, 2024 (GLOBE NEWSWIRE) -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, today announced a plan to optimize its resource allocation, restructure, and extend runway to focus resources on key programs in the Company's pipeline, including the ongoing phase 1/2 study of KB-0742 following the review of additional positive preliminary safety and efficacy data. This plan positions the Company to maximize the potential of KB-0742, an inhibitor of CDK9, by exploring an extended dosing schedule while also continuing to progress KB-9558, a p300 KAT inhibitor, through ongoing IND-enabling studies and into the clinic, and its discovery efforts and collaborations. The Company expects these efforts, which include a 21% reduction in force, will extend cash runway into the second half of 2026.

To date, anti-tumor activity has been observed without grade 3/4 neutropenia in patients treated with KB-0742 at doses ranging from 10mg to 80mg using the current three-days-on, four-days-off dosing schedule. The Company has reported target engagement, tumor regressions, and an acceptable safety profile at 60mg dosed three-days-on, four-days-off. KB-0742 cleared 80mg three-days-on, four-days-off and the Company expects to publish this data in addition to the 60mg expansion mid-year. As disclosed earlier this week, the Company plans to escalate to 80mg four-days-on, three-days-off, a dosing schedule that offers patients significantly increased time at or above a therapeutic threshold compared to the already established active dose of 60mg dosed three-days-on, four-days-off. The amended protocol leverages a 3+3 design, placing the Company on a path to efficiently clear the dose levels, and the Company expects to share topline data from the expansion cohort at this dose schedule in the first half of 2025.

"We are committed to exploring the promise of our pipeline. Building upon the positive data for KB-0742 that we have previously reported, these measures enable us to assess the potential for additional clinical benefit of the drug at an extended dosing schedule in patients with transcriptionally addicted tumors," said Norbert Bischofberger, Ph.D., president and chief executive officer of Kronos Bio. "The measures we have taken today, while difficult, will streamline our operations, extend our runway, and best position us to advance our maturing discovery projects, including our collaboration with Genentech, and to advance KB-9558 through IND-enabling studies and into the clinic. I want to express my gratitude to all our employees, including those departing Kronos Bio today, for their contributions to our mission to bring forward new and innovative therapies for difficult-to-treat cancers."

In December, KB-0742 cleared the 80mg dose in the dose escalation portion of the phase 1/2 trial using a three-days-on, four-days-off dosing schedule. Before escalating to the planned dosing schedule of 80mg four-days-on, three-days-off, the Company is currently evaluating 60mg of KB-0742 four-days-on, three-days-off in three evaluable patients as contemplated by a 3+3 design. If the safety profile of KB-0742 remains acceptable, the Company will then evaluate safety in three additional patients at 80mg four-days-on, three-days-off prior to enrolling patients in an expansion cohort. The Company currently contemplates the expansion cohort will include patients with either small cell or non-small cell lung cancer, ovarian cancer, or triple negative breast cancer, and expects to provide an update later in the year on which tumor type(s) will be included in the expansion cohort.

The Company intends to present updated data at a medical meeting in mid-2024 based on data that have been collected from patients who have received doses of KB-0742 of 60mg or 80mg using the prior three-days-on, four-days-off dosing schedule. In the third quarter of 2024, the Company expects to provide an update from the new four days per week dosing schedule and announce its plans for the dose expansion portion of the phase 1/2 trial. In the first half of 2025, Kronos Bio plans to present topline safety and efficacy data at a medical meeting from patients on the new four-days-on, three-days-off dosing schedule.

On April 8, 2024, Kronos Bio will present preclinical data on KB-9558 in multiple myeloma at the American Association for Cancer Research (AACR) annual meeting in San Diego, California. Pending the completion of IND-enabling studies in 2024, the Company expects to commence a first-in-human study in multiple myeloma in 2025.

About Kronos Bio, Inc.

Kronos Bio is a biopharmaceutical company that is advancing an investigational CDK9 inhibitor compound, KB-0742, in a Phase 1/2 clinical trial as a treatment for MYC-amplified solid tumors and other transcriptionally addicted solid tumors as well as a preclinical development candidate, KB-9558, targeting the KAT domain of p300 for multiple myeloma. The Company's scientific focus is on developing medicines that target deregulated transcription, 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 https://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," "believe," "could," "expect," "on track," "plan," "potential," "promising," "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, Kronos Bio's plans to implement the amended Phase 1/2 KB-0742 study protocol and to complete IND-enabling studies for KB-9558; the expected timing for additional clinical data from the Phase 1/2 KB-0742 study; the potential to bring KB-9558 to the clinic; future pipeline development activities or outcomes; future organizational efficiencies or other benefits from the strategic realignment and reduction in force; the potential of Kronos Bio's product candidates; Kronos Bio's expected cash runway; expected future savings; 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: risks associated with changes to the assumptions underlying estimated charges or expected future savings; changes in the macroeconomic environment or competitive landscape that impact Kronos Bio's business; whether Kronos Bio will be able to progress its clinical trials on the timelines anticipated, including due to risks inherent in the clinical development of novel therapeutics; risks related to Kronos Bio's limited experience as a company in conducting clinical trials; the risk that results of preclinical studies and early clinical trials (including preliminary results) are not necessarily predictive of future results; and 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 September 30, 2023, filed with the SEC on November 13, 2023. 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.

Investor & Media Contact:
Margaux Bennett
Vice President, Corporate Development and Investor Relations, Kronos Bio
650-781-5026
mbennett@kronosbio.com