Kronos Bio Announces Positive Data from Ongoing Phase 1/2 Trial of Oral CDK9 Inhibitor KB-0742

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Initial data demonstrate long plasma half-life and dose-dependent target inhibition

Trial is continuing to enroll patients on three-day on, four-day off schedule

SAN MATEO, Calif. and CAMBRIDGE, Mass., Nov. 29, 2021 (GLOBE NEWSWIRE) -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, today announced positive data from the ongoing Phase 1/2 clinical trial of KB-0742, the company's internally discovered, highly selective, oral cyclin dependent kinase 9 (CDK9) inhibitor being developed to treat MYC-amplified solid tumors.

An interim analysis of the ongoing dose escalation stage of the trial (data cut-off October 29) demonstrated a differentiated pharmacokinetic (PK) profile and evidence of target engagement for KB-0742. The PK analysis showed oral bioavailability and dose-proportional exposure across the first three dose levels, with low to moderate variability between patients. Among the 12 patients treated in the trial, KB-0742 had a terminal half-life of 24 hours, with approximately 2 to 2.5-fold accumulation between Day 1 and Day 10. This long plasma half-life supports Kronos Bio's approach to defining a therapeutic window for CDK9 inhibition. Proprietary target engagement assays developed and prospectively validated by Kronos Bio demonstrated dose-dependent reduction of phosphorylation of Ser2 on RNA Polymerase II (pSer2), a direct substrate target of CDK9, as well as reduced expression of CDK9-dependent genes in peripheral blood mononuclear cells from patients at each of the three dose levels. Consistent with the company's preclinical modeling, further dose escalation is required to reach desired levels of CDK9 inhibition. The nature and severity of the adverse events observed has been consistent with what is typically seen among heavily pretreated patients with advanced cancer in Phase 1 trials, and Kronos Bio is continuing to enroll the trial.

"We are pleased with the early findings from this trial, which demonstrate that KB-0742 is showing a differentiated PK profile and a level of target engagement in patients that we had predicted based on our preclinical studies," said Norbert Bischofberger, Ph.D., president and chief executive officer of Kronos Bio. "These early data are encouraging, and we look forward to continuing the trial and establishing a recommended Phase 2 dose."

The trial consists of two stages. The first and ongoing stage is assessing the safety, PK and PD profile of KB-0742. This dose escalation stage is designed to define, as efficiently as possible, the recommended Phase 2 dose (RP2D) and schedule and is not specifically enrolling patients based on MYC status, which would lengthen the timeline. The second stage of the trial will enroll patients with MYC-amplified or over-expressing tumors, as well as other transcriptionally addicted tumor types to assess the anti-tumor activity of KB-0742 at the RP2D.

Kronos Bio is continuing to enroll patients in the dose-escalation stage of the study and anticipates presenting data from the study at a future medical conference.

About Kronos Bio, Inc.
Kronos Bio is a clinical-stage biopharmaceutical company dedicated to discovering and developing therapies that seek to transform the lives of those affected by cancer. The company focuses on targeting dysregulated transcription factors and the regulatory networks within cells that drive cancerous growth. Kronos Bio's lead investigational therapy is entospletinib, a selective inhibitor targeting spleen tyrosine kinase (SYK) in development for the frontline treatment of NPM1-mutated acute myeloid leukemia (AML). The company is also developing KB-0742, an oral inhibitor of cyclin dependent kinase 9 (CDK9), for the treatment of MYC-amplified solid tumors.

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. This press release, in some cases, uses terms such as "will," "anticipates" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our plan to continue enrolling patients in the Phase 1/2 clinical trial of KB-0742; the design of such Phase 1/2 clinical trial and expected future progress and activities, including in relation to the second stage of the trial and establishing a recommended Phase 2 dose; our expectation to present data from such Phase 1/2 clinical trial at a future medical conference; 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: whether we will be able to complete ongoing enrollment for the Phase 1/2 clinical trial of KB-0742 on the timeline expected, or at all, including due to risks associated with the COVID-19 pandemic; risks inherent in the clinical development of novel therapeutics; risks related to our lack of experience as a company in conducting clinical trials; and risks associated with the sufficiency of our cash resources and need for additional capital. These and other risks and uncertainties are described in greater detail in the company's filings with the Securities and Exchange Commission ("SEC"), including under the heading "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2021, filed with the SEC on November 9, 2021. 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, the company 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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