Kronos Bio Announces FDA Clearance of Investigational New Drug (IND) Application for KB-0742, an Oral CDK9 Inhibitor Targeting MYC-amplified Cancers

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MYC amplification found in approximately 30% of solid tumors

Phase 1/2 clinical trial to begin in the first quarter of 2021

KB-0742 generated using the company's proprietary small molecule microarray (SMM) screening platform

SAN MATEO, Calif., and CAMBRIDGE, Mass., Dec. 07, 2020 (GLOBE NEWSWIRE) -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, today announced U.S. Food and Drug Administration (FDA) clearance of the company's Investigational New Drug (IND) application for KB-0742, a highly selective, orally bioavailable inhibitor of cyclin dependent kinase 9 (CDK9). The company plans to begin a Phase 1/2 clinical trial of KB-0742 in patients with advanced solid tumors in the first quarter of 2021.

"CDK9 is an important transcriptional co-factor of MYC, a well-known driver of cancer that is amplified in approximately 30 percent of solid tumors," said Norbert Bischofberger, Ph.D., president and CEO. "FDA clearance of the IND for KB-0742 marks an important milestone for this program, which was generated using our proprietary drug discovery platform. In the next few months, we look forward to initiating a first-in-human clinical trial designed to define a dose and schedule which affords appropriate target engagement and acceptable safety, setting the stage for potential further development of this promising investigational therapy."

The open-label, Phase 1/2 clinical trial for KB-0742 will be conducted over two stages: dose escalation and expansion. The dose-escalation stage will assess the safety, pharmacokinetic (PK) and pharmacodynamic (PD) profile of KB-0742 and seek to establish a pharmacologically active dose and schedule with an acceptable safety profile. This dose and schedule will be further studied in the subsequent expansion stage in patients with MYC-amplified solid tumors and other transcriptionally addicted rare tumors such as sarcomas and chordomas. Kronos Bio expects to report initial safety, PK and PD data from the dose-escalation stage of the study in 2021.

About KB-0742
KB-0742 is a highly selective, orally bioavailable inhibitor of cyclin dependent kinase 9 (CDK9) in development for the treatment of MYC-amplified solid tumors. CDK9 is a global regulator of transcription and plays an essential role in the expression and function of MYC, a well-characterized transcription factor and a long-recognized driver of cancer that is amplified in approximately 30 percent of solid tumors, including those affecting the lungs, ovaries, esophagus, breast, stomach, pancreas and liver. KB-0742 was generated and optimized from a compound that was identified using the company's proprietary small molecule microarray (SMM) screening platform.

About Kronos Bio, Inc.
Kronos Bio is a clinical-stage biopharmaceutical company dedicated to discovering, developing and commercializing 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. The press release, in some cases, uses terms such as "designed," "look forward," "promising," "believes," "potential," "expects," "plans," "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 begin a Phase 1/2 clinical trial of KB-0742 in patients with advanced solid tumors and the expected timing thereof; the design of such planned Phase 1/2 clinical trial, including to establish clinical proof of concept to enable potential further development; Kronos Bio's expectation to report data from such planned Phase 1/2 clinical trial and the expected timing thereof; 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 Kronos Bio will be able to initiate or complete the Phase 1/2 clinical trial of KB-0742 on the timeline expected, if at all, 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; the risk that due to the relatively small number of patients that Kronos Bio plans to dose in the planned Phase 1/2 clinical trial, the results from the planned Phase 1/2 clinical trial, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder Kronos Bio's efforts to further develop and obtain regulatory approval for KB-0742; 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, 2020, filed with the SEC on November 18, 2020. 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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