Kronos Bio Presents Positive Preliminary Data from the Phase 1 Dose Escalation Portion of the Ongoing Phase 1/2 KB-0742 Study at the Connective Tissue Oncology Society Annual Meeting

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Brian Van Tine, M.D., of Washington University School of Medicine, shares data from the ongoing phase 1/2 KB-0742 clinical study that clearly corresponds with the findings from the pre-clinical studies at leading international sarcoma meeting

KB-0742 demonstrated on-mechanism, single agent anti-tumor activity and a manageable safety profile in heavily pre-treated patients with transcriptionally addicted solid tumors

SAN MATEO, Calif. and CAMBRIDGE, Mass., Nov. 02, 2023 (GLOBE NEWSWIRE) -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, today announced the presentation of positive preliminary data from the phase 1 dose escalation portion of the ongoing phase 1/2 KB-0742 study at the Connective Tissue Oncology Society annual meeting in Dublin, Ireland. Today’s presentation by Dr. Van Tine of Washington University School of Medicine includes clinical data that was first presented at the AACR-NCI-EORTC International Conference on October 13, 2023, in Boston, Massachusetts in the context of pre-clinical models that provide a better understanding of the observed anti-tumor activity. Preclinical studies led by Berkley Gryder, PhD, of Case Western Reserve University demonstrated KB-0742’s on-mechanism activity in transcription factor fusion positive models for rhabdomyosarcoma and Ewing sarcoma.

“Sarcomas are very complex to diagnose and treat so there is a significant need for innovation in this field,” said Brian Van Tine, M.D., of Washington University School of Medicine in St. Louis. “I am very encouraged by the positive preliminary KB-0742 data, not only for what it could mean for sarcoma patients, but also for other cancer types given evidence of on-mechanism clinical activity and a manageable safety profile. Today, I shared a case study on one of my sarcoma patients who exhausted all standard therapies as well as multiple experimental treatments. This patient received KB-0742 for more than a year and experienced objective clinical benefit, including the shrinkage of their tumor. I look forward to learning more about the utility of KB-0742 from the ongoing dose escalation and expansion studies.”

“We now have positive preliminary KB-0742 clinical efficacy and safety data that corresponds with what we saw in the read-outs from the pre-clinical mechanistic studies,” said Jorge DiMartino M.D., Ph.D., Chief Medical Officer and Executive Vice President, Clinical Development. “Data show that KB-0742 reduces expression of oncogenic TF fusions and this translates into anti-tumor activity. This further bolsters our confidence that the drug is behaving the way we expected.”

KB-0742 is Kronos Bio’s internally discovered, highly selective, orally bioavailable cyclin dependent kinase 9 (CDK9) inhibitor being developed to treat transcriptionally addicted solid tumors, including small cell lung cancer, sarcomas with transcription factor fusion genes and MYC-dependent tumors, such as triple negative breast, ovarian, and lung cancer. The preliminary analysis included 28 patients enrolled in a dose escalation study who received doses from 10 mg up to 60 mg (data cut-off September 1st, 2023). KB-0742 demonstrated on-mechanism single agent anti-tumor activity in heavily pre-treated patients with transcriptionally addicted tumor types and exhibited a manageable safety profile, with no grade 3/4 neutropenia. KB-0742 also demonstrated dose proportional exposure, dose-dependent target engagement, and 24-hour plasma half-life.

The most prevalent treatment-emergent adverse events (TEAEs) included nausea (64%), vomiting (68%) and fatigue (29%), all of which were grade 1/2. No grade 3/4 neutropenia was observed, and no treatment-related deaths were observed. The most common reasons for treatment discontinuation were progressive disease, TEAEs, and withdrawal of consent.


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 other transcriptionally addicted solid tumors and lanraplenib, a next-generation SYK inhibitor, for patients with FLT3-mutated acute myeloid leukemia. The company’s scientific focus is on developing medicines that target the deregulated 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 “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, Kronos Bio’s the expected timing for data from the dose expansion portion of the study, the promise of KB-0742 to treat patients with transcriptionally addicted tumors, KB-0742 being a promising agent to treat a wide variety of cancers with high unmet need, future results that may be implied from preliminary data, 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 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 lack of experience as a company in conducting clinical trials; and the risk that results of preclinical studies and early clinical trials (including preliminary
results) are not necessarily predictive of future results. 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, 2023, filed with the SEC on August 8, 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.

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