Kronos Bio to Present Clinical Update on Phase 1/2 Trial of KB-0742 at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting

May 23, 2024

—KB-0742 continues to demonstrate a manageable safety and tolerability profile with no grade 3/4 neutropenia observed —

— KB-0742 continues to show dose linear pharmacokinetics up to 80mg three-days-on, four-days-off dose, including increased target engagement at the 80mg vs. 60mg doses —

— The escalation cohort at 80mg four-days-on, three-days-off is currently enrolling, and the expansion cohort at this dose is expected to begin enrollment in the third quarter of 2024 —

SAN MATEO, Calif. and CAMBRIDGE, Mass., May 23, 2024 (GLOBE NEWSWIRE) -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to developing small molecule therapeutics that address cancers and other diseases driven by deregulated transcription, today announced the presentation of new data from its ongoing Phase 1/2 study, KB-0742-1001, a first-in-human, open-label dose escalation and cohort expansion study of KB-0742 in patients with relapsed or refractory solid tumors or non-Hodgkin lymphoma, in a poster session at the 2024 American Society for Clinical Oncology (ASCO) Annual Meeting being held from May 31 – June 4, 2024 in Chicago, Illinois and online.

“We are pleased that KB-0742 continues to demonstrate a manageable safety and tolerability profile as it progresses through dose escalation,” said Norbert Bischofberger, Ph.D., president and chief executive officer, Kronos Bio, Inc. “These data indicate a deepening reduction of CDK9-sensitive transcripts at the 80mg dose as compared to the 60mg dose. In addition, MYC reductions were observed in paired biopsy tumor tissues. This data provides us with confidence that the 80mg four-days-on, three-days-off dose and schedule will show increased patient benefit. We are currently enrolling the dose escalation arm at the 80mg four-days-on, three-days-off schedule and look forward to opening the expansion cohort in the third quarter of this year.”

The poster features:

- Data from 103 patients with transcription factor (TF) fusion or MYC driven tumors treated with KB-0742 at 60mg (n=82) and 80 mg (n=21) three-days-on/four-days-off in escalation and expansion cohorts.
- Patients enrolled in the study had received a median of three prior treatments (range: 0-9).
- The most frequently reported treatment-emergent adverse events (AE) were manageable mild to moderate nausea (69.9%) and vomiting (52.4%).
- Notably, no grade 3/4 neutropenia was observed.
- Patients remained on treatment for an average of >2 cycles and a maximum of 14 completed cycles.
- Less than 10% of patients discontinued treatment due to adverse events.
- Two case studies, a platinum-resistant ovarian cancer (OC) patient, and a non-small-cell-lung cancer (NSCLC) patient with five prior lines of therapy will be presented. These patients exhibited anti-tumor activity including stable disease responses of 71 days for the NSCLC patient and greater than 195 days for the OC patient, who continues on therapy.
- Pharmacokinetic modeling indicates that the 80mg four-days on three-days off dose schedule results in a greater than ten-fold increase in time above a preclinically determined efficacy threshold compared to the 60mg three-days-on four-days-off dose schedule.

Based on the promising initial data presented at ASCO and the pharmacokinetic modeling the Company expects to see increased efficacy in the 80mg four-day-on, three-day-off expansion cohort which is expected to begin enrolling in the third quarter of 2024.

Preliminary efficacy data was presented at the 2023 AACR-NCI-EORTC meeting in October 2023 showing KB-0742’s on-mechanism anti-tumor activity in transcriptionally addicted tumors including a partial response at the 60mg three-days-on, four-days-off dose schedule.

Details for the ASCO 2024 abstract are as follows:

Title: Study update of the oral CDK9 inhibitor KB-0742 in relapsed or refractory transcriptionally addicted advanced solid tumors
Presenter: Brian A. Van Tine, M.D., Ph.D., Washington University in St. Louis
Abstract ID#: 3102
Poster Session: Developmental Therapeutics—Molecularly Targeted Agents and Tumor Biology
Location: Hall A, McCormick Place, Chicago, Illinois
Poster Board #: 247
Date and Time: Saturday, June 1, 2024, from 9:00 a.m. to 12:00 p.m. CDT

About Kronos Bio, Inc.

Kronos Bio, Inc (Nasdaq: KRON) is a clinical-stage company dedicated to developing small molecule therapeutics that address deregulated transcription, a hallmark of cancer and other diseases. Our proprietary discovery engine decodes complex transcription factor (TF) regulatory networks to identify druggable cofactors. We screen for and optimize small molecules that target these cofactors in a tumor-specific context. These efforts have yielded a preclinical pipeline along with two internally developed drug candidates. KB-0742 targets CDK9 to address MYC deregulation in

solid tumors and KB-9558 targets p300 to address IRF4 dependence in multiple myeloma.

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.

About KB-0742:

KB-0742 is a selective, oral inhibitor of CDK9, a key cofactor of oncogenic MYC transcription factor activity. KB-0742-1001 (NCT04718675) is a Phase 1/2 open-label dose escalation and cohort expansion study of KB-0742 as a treatment for *MYC*-amplified and other transcriptionally addicted relapsed or refractory solid tumors.

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," "plan," "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 next clinical update on KB-0742; the expected timing of enrollment of the 80mg expansion cohort of the KB-0742 trial; the expectation of increased efficacy and increased patient benefit of KB-0742 in the 80mg expansion cohort; the potential of Kronos Bio's product candidates and its proprietary discovery engine; 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: 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; risks associated with completing necessary preclinical studies and receiving regulatory clearance for, and enrolling, clinical trials; 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 March 31, 2024, filed with the SEC on May 9, 2024. 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.

Source: Kronos Bio, Inc.

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