Kronos Bio Presents Preclinical Data Supporting Anti-Leukemic Activity of Lanraplenib in Combination with Multiple Targeted Agents in Acute Myeloid Leukemia (AML) Preclinical Models at American Society of Hematology Meeting

December 11, 2022

Lanraplenib is being evaluated in ongoing Phase 1b/2 trial in combination with gilteritinib in patients with relapsed/refractory FLT3-mutated AML

Additional presentations highlight Kronos Bio's collaboration with academic cooperative groups to better understand the predictive value of measurable residual disease

SAN MATEO, Calif. and CAMBRIDGE, Mass., Dec. 11, 2022 (GLOBE NEWSWIRE) -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, is presenting preclinical data that demonstrate anti-leukemic activity of the investigational spleen tyrosine kinase (SYK) inhibitor, lanraplenib, in combination with multiple targeted agents in patient-derived cell isolates and cell lines at the 64th American Society of Hematology (ASH) Annual Meeting & Exposition in New Orleans. The data are being shared as part of a poster presentation.

Lanraplenib is a next-generation SYK inhibitor that is currently being evaluated in combination with gilteritinib in patients with relapsed/refractory *FLT3*-mutated acute myeloid leukemia (AML) in a Phase 1b/2 study. The company anticipates sharing initial data from the lanraplenib/gilteritinib trial, along with the recommended Phase 2 dose (RP2D), in the fourth quarter of 2023 or first quarter of 2024.

Researchers evaluated lanraplenib and a second SYK inhibitor, entospletinib, which the company has discontinued developing, in combination with a menin inhibitor (SNDX5613), in two cell lines with FLT3 internal tandem duplication/MLL rearrangement. Synergistic anti-proliferative effects were observed across a broad range of concentrations. The combination triggered differentiation and apoptosis, suggesting a more complete blockade of the *HOXA9/MEIS1* transcriptional program through synergistic inhibition by orthogonal mechanisms.

Additionally, the researchers evaluated synergistic activity of lanraplenib with the FLT3 inhibitor, gilteritinib, and BCL2 inhibitor, venetoclax, in patient-derived AML isolates. This analysis found synergistic anti-proliferative activity for both combinations. Patient-derived xenograft (PDX) studies also demonstrated deeper reductions in leukemic burden in the peripheral blood and bone marrow after 28 days of treatment with lanraplenib and gilteritinib. In a follow-up PDX study with an optimized regimen, the combination significantly extended overall survival compared to either single agent.

"These data further support the biological rationale for SYK inhibition as a treatment for AML," said Jorge DiMartino, M.D., Ph.D., chief medical officer and executive vice president of Clinical Development for Kronos Bio. "We believe that lanraplenib has the potential to one day be the cornerstone of targeted therapy-based regimens for the treatment of genetically defined AML, and these data add to the evidence that supports that belief."

Kronos Bio also presented two posters at the meeting focused on increasing the understanding of measurable residual disease (MRD) negative CR as a surrogate endpoint in AML trials. One poster analyzed MRD and survival data from 1,128 patients with *NPM1*-mutated AML in three cooperative group trials, confirming that achieving MRD negative CR predicts better overall and event-free survival. A second poster described the development of a next generation sequencing-based assay for measuring MRD and compared the performance of this assay against the gold standard RT-qPCR based method.

"Kronos Bio has been an industry leader in pioneering the use of MRD in the development of novel treatments for patients with AML in a more efficient manner," said Dr. DiMartino. "We believe that our continued efforts in this space will help to advance the field and our own AML pipeline."

Presentation information
Poster Title: SYK Inhibitors, Entospletinib and Lanraplenib, Show Potent Anti-Leukemic Activity in Combination with Targeted Agents
Abstract Number: 2639
Date and Time: Sunday, December 11, 2022, 6-8 p.m. CT

Additional posters

Poster Title: Analysis of Patient-Level Data From 3 Cooperative Group Trials Confirms a Survival Advantage for *NPM1*m Patients Achieving MRD-Negative CR after Intensive Induction
Abstract Number: 2799
Date and Time: Sunday, December 11, 2022, 6-8 p.m. CT

Poster Title: Development of a Standardized, DNA-Based Next Generation Sequencing Assay for Assessment of Measurable Residual Disease (MRD) in Acute Myeloid Leukemia (AML) as the Primary Endpoint in the AGILITY Study
Abstract Number: 1463
Date and Time: Saturday, December 10, 2022, 5:30-7:30 p.m. CT

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 lanraplenib, a next-generation SYK inhibitor, for patients with relapsed/refractory *FLT3*-mutated acute myeloid leukemia. The company's scientific focus is on developing medicines that target the dysregulated 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. This press release, in some cases, uses terms such as “to be,” “will,” “expects,” “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 expectation to share initial data from the lanraplenib/gilteritinib trial, along with the RP2D, in the fourth quarter of 2023 or first quarter of 2024; our belief that lanraplenib has the potential to one day be the cornerstone of targeted therapy-based regimens for the treatment of genetically defined AML; our belief that our use of MRD in the development of novel treatments for patients with AML will help to advance the field and our own AML pipeline; 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 inherent in the clinical development of novel therapeutics; MRD has only recently emerged as a surrogate endpoint for progression free survival in hematological malignancies, and while regulatory approvals on the basis of MRD status have been granted in acute lymphocytic leukemia and chronic lymphocytic leukemia, to date there have not been any regulatory approvals on the basis of MRD status in AML; 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, 2022, filed with the SEC on November 8, 2022. 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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