Kronos Bio and Invivoscribe Partner on Companion Diagnostic for Use with Entospletinib, Kronos Bio's Investigational Compound Being Developed for Patients with AML

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Companion diagnostic would be used following potential regulatory approval of entospletinib to screen for NPM1 mutation present in approximately one-third of all patients with AML

Entospletinib is currently being studied in the Phase 3 AGILITY registrational study, with data anticipated in second half of 2023

SAN MATEO, Calif. and SAN DIEGO, Aug. 16, 2022 (GLOBE NEWSWIRE) -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, and Invivoscribe, a global provider of diagnostic kits and services for oncology, today announced their agreement to develop a companion diagnostic (CDx) for use with Kronos Bio's investigational therapy, entospletinib. Entospletinib is Kronos Bio's lead clinical compound, currently in the ongoing Phase 3 registrational AGILITY study for the treatment of newly diagnosed NPM1-mutated acute myeloid leukemia (AML).

The diagnostic will screen for the NPM1 mutation, which is present in approximately one-third of all patients with AML.

Over the past year, the two companies have worked together to develop and advance the diagnostic and prepare to submit the Premarket Approval (PMA) application to the U.S. Food and Drug Administration (FDA) at the same time as the submission of the entospletinib New Drug Application (NDA). The FDA requires the validation and approval of companion diagnostics used to select patients for treatment with a specific therapeutic agent.

The agreement builds on Invivoscribe's experience in developing and obtaining approval for diagnostics used for identification of patients with genetically mutated AML. Invivoscribe markets an FDA-approved CDx for FLT3-mutated AML.

"This companion diagnostic NPM1 mutation assay development work with Kronos Bio represents a significant milestone for our company," said Jeffrey Miller, Ph.D., chief scientific officer and chief executive officer of Invivoscribe. "Companion diagnostics play a key role in the development and approval of targeted drug therapies and these kinds of partnerships are critical to improving care for patients with cancer."

Kronos Bio's AGILITY trial is designed to assess the efficacy and safety of entospletinib in approximately 180 adults who have been newly diagnosed with NPM1-mutated AML. In the trial, patients are being randomized to receive entospletinib or placebo, in combination with standard induction and consolidation chemotherapy. The primary endpoint of the trial is measurable residual disease (MRD) negative complete response. Event-free survival (EFS) is a key secondary endpoint, and mature EFS data are anticipated to be used to support potential full approval.

"The development of the NPM1 mutation companion diagnostic is a critical step in our efforts to rapidly advance entospletinib," said Jorge DiMartino, M.D., Ph.D., chief medical officer and executive vice president, Clinical Development at Kronos Bio. "We are fortunate to benefit from Invivoscribe's prior experience in bringing to market companion diagnostics for patients with AML."

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.

About Invivoscribe

Invivoscribe has focused on Improving Lives with Precision Diagnostics® for more than 28 years, advancing the field of precision medicine by developing and selling standardized reagents, tests, and bioinformatics tools to more than 700 customers in 160 countries. Invivoscribe also has a significant impact on global health working with pharmaceutical companies to accelerate approvals of new drugs and treatments by supporting international clinical trials, developing, commercializing companion diagnostics, and providing expertise in both regulatory and laboratory services. With its proven ability to provide global access to distributable reagents, kits, and controls, as well as clinical trial services through our international clinical lab subsidiaries (LabPMM), Invivoscribe has demonstrated it is an ideal partner. For additional information please visit: www.invivoscribe.com or contact Invivoscribe at: customerservice@invivoscribe.com.

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 "anticipated," "designed," "following," "potential," "prepare," "will," "would" 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 potential successful development of a companion diagnostic for use with entospletinib; the potential submission of a PMA for such companion diagnostic; the potential validation and regulatory approval of the companion diagnostic and its use with entospletinib following approval; the potential regulatory approval of entospletinib; the anticipated use of mature EFS data to support potential full approval of

entospletinib; the anticipated timing for data from the AGILITY trial; the design of the AGILITY trial; 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 and Invivoscribe will be able to successfully develop a companion diagnostic for use with entospletinib on the timeline expected, or at all, including risks related to contractual performance and Kronos Bio's reliance on Invivoscribe to complete the validation of the companion diagnostic necessary to meet regulatory requirements; whether Kronos Bio will be able to initiate, progress or complete the AGILITY trial on the timeline expected, or at all, 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 are not necessarily predictive of future results; risks related to regulatory approval of novel therapeutic products and companion diagnostics, including the risk that lack of approval of a companion diagnostic (including the companion diagnostic being developed for use with entospletinib) may jeopardize approval of the novel therapeutic product (including entospletinib); 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 June 30, 2022, as filed with the SEC on August 4, 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, 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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