Kronos Bio Announces First Patient Dosed in Phase 1b/2 Clinical Trial of Lanraplenib in Combination with Gilteritinib in Acute Myeloid Leukemia

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SAN MATEO, Calif., Aug. 22, 2022 (GLOBE NEWSWIRE) -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, today announced that the first patient has been dosed in a Phase 1b/2 clinical trial of lanraplenib in combination with gilteritinib in patients with relapsed/refractory FLT3-mutated acute myeloid leukemia (AML).

Lanraplenib is the company's next-generation spleen tyrosine kinase (SYK) inhibitor. In addition to lanraplenib, Kronos Bio is also evaluating its lead investigational SYK inhibitor, entospletinib, in the Phase 3 registrational AGILITY study as a treatment for newly diagnosed patients with NPM1-mutated AML in combination with standard induction and consolidation chemotherapy. While entospletinib and lanraplenib have equivalent preclinical anti-leukemic activity and selectivity for SYK, lanraplenib's pharmacologic properties may be advantageous in regimens that are dosed to progression, such as the investigational gilteritinib combination.

The Phase 1b/2 lanraplenib clinical trial is a multi-center, open-label, dose-escalation study enrolling patients with relapsed/refractory FLT3-mutated AML. This trial is being conducted in two stages: a dose-escalation stage and an expansion stage. The first stage is evaluating initial safety, pharmacokinetic and anti-leukemic activity of escalating once-daily doses of lanraplenib in combination with the standard approved dose of gilteritinib. This stage also will assess FLT3 measurable residual disease (MRD) negative rate in patients who achieve a complete response (CR) and explore the predictive value of a number of biomarkers that may correlate with clinical outcomes.

Once a recommended dose is established, an expansion stage is planned to further evaluate the safety of lanraplenib and assess its anti-leukemic activity as measured by CR rate and duration of response.

"The initiation of this study is an important first step as we advance lanraplenib for patients with certain genetically defined types of AML," said Jorge DiMartino, M.D., Ph.D., chief medical officer and executive vice president of Clinical Development at Kronos Bio. "Our long-term vision is to develop lanraplenib as a cornerstone of targeted regimens for these patients, allowing us to potentially reach as many as two-thirds of patients with AML. Today's announcement represents important progress toward that goal."

Kronos Bio currently has three investigational compounds in clinical development. In addition to the SYK inhibitors, which were acquired from Gilead Sciences, Inc., the company is advancing KB-0742, a highly selective, orally bioavailable inhibitor of cyclin dependent kinase 9 (CDK9) as a treatment for MYC-amplified solid tumors. KB-0742 is currently being studied in a Phase 1/2 trial and is the first compound discovered through the company's proprietary small molecule microarray (SMM) screening platform.

Learn more about Krono Bio's clinical trials here.

About Acute Myeloid Leukemia

Acute myeloid leukemia (AML) primarily affects adults and is one of the most difficult-to-treat blood cancers. AML starts in the bone marrow, impairing its ability to produce mature red blood cells, white blood cells and platelets. Without treatment, patients die within weeks to months from progressive bone marrow failure leading to infections, bleeding and heart failure. Approximately 20,000 people are diagnosed with AML in the United States each year, with FLT3 genetic mutations found in approximately one-third of cases. Relapse in AML is common, and despite available treatments, almost 11,000 people die from the disease each year in the United States.

About Lanraplenib

Kronos Bio is developing lanraplenib, a next-generation selective inhibitor targeting spleen tyrosine kinase (SYK), for the treatment of patients with relapsed/refractory FLT3-mutated acute myeloid leukemia (AML). Lanraplenib has been investigated in more than 250 healthy volunteers and patients with autoimmune diseases. In preclinical studies, lanraplenib was shown to have anti-leukemic activity against NPM1-mutated and FLT3-mutated AML samples.

About Kronos Bio, Inc.

Kronos Bio is a biopharmaceutical company that is advancing three investigational compounds in clinical trials for patients with cancer. The company's lead compound, the SYK inhibitor entospletinib, is being evaluated in the registrational Phase 3 AGILITY trial as a treatment for patients with newly diagnosed NPM1-mutated acute myeloid leukemia (AML). The company is also developing the CDK9 inhibitor, KB-0742, as a treatment for MYC-amplified solid tumors and lanraplenib, a next-generation SYK inhibitor being assessed in patients with FLT3-mutated AML. 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. The press release, in some cases, uses terms such as "goal," "long-term," "may," "plan," "vision," "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:

lanraplenib's pharmacologic properties and potential advantages; the design of the Phase 1b/2 lanraplenib clinical trial; future clinical trial activities and goals; Kronos Bio's long-term vision for lanraplenib; 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 or complete any of its ongoing clinical trials on the timelines expected, if 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; 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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