Kronos Bio to Highlight Progress Across Pipeline and Outline Growth Strategy at Virtual R&D Day Today

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Unveils development strategy for lanraplenib (LANRA), which will expand addressable patient population for SYK inhibitor portfolio in acute myeloid leukemia (AML); plans to initiate two Phase 1/2 trials in late 2021 and early 2022

On track to initiate registrational Phase 3 trial for entospletinib (ENTO) in newly diagnosed NPM1-mutated AML in mid-2021

Outlines potential target indications based on recent preclinical data for CDK9 inhibitor KB-0742, in development to treat MYC-dependent solid tumors; initial safety, PK and PD data readout from ongoing Phase 1/2 trial expected in the fourth quarter of 2021

Highlights unique capabilities of discovery product engine that enables selective targeting of transcription factors and transcriptional regulatory networks that drive cancer

SAN MATEO, Calif. and CAMBRIDGE, Mass., May 25, 2021 (GLOBE NEWSWIRE) -- Kronos Bio, Inc. (Nasdaq: KRON), a company dedicated to transforming the lives of those affected by cancer, will host a virtual R&D Day today to detail the development strategy for its spleen tyrosine kinase (SYK) inhibitor portfolio, and highlight the momentum of its cyclin-dependent kinase 9 (CDK9) inhibitor program and the company's ability to target transcription factors and transcriptional regulatory networks that drive cancer. The webinar will begin at 1:00 p.m. ET and can be accessed here.

"Transcription factors and their associated regulatory networks have long been known to drive cancerous cell growth but have eluded therapeutic approaches. We are excited to present our progress in understanding and targeting transcriptional regulatory networks that drive small cell lung cancer and castration-resistant prostate cancer. We also look forward to sharing our roadmap for the continued development of novel cancer therapeutics that have the potential to address high unmet needs," said Norbert Bischofberger, Ph.D., president and CEO. "Today, we are announcing our plans to initiate two Phase 1/2 clinical trials for LANRA in patients with relapsed/refractory FLT3-mutated AML and in patients newly diagnosed with NPM1-mutated AML who are not candidates for intensive induction chemotherapy. The LANRA trials build upon the significant progress we have made over the past year, which includes advancing ENTO toward a registrational Phase 3 clinical trial that may support accelerated approval to treat newly diagnosed NPM1-mutated AML patients eligible for intensive induction chemotherapy and initiating a Phase 1/2 clinical trial for KB-0742, our oral CDK9 inhibitor targeting MYC-dependent solid tumors."

"ENTO and LANRA are differentiated clinical-stage SYK inhibitors that have the potential to address patients with mutations present in more than two-thirds of AML. Our development strategy for these complementary therapies seeks to leverage their properties to address the treatment needs of patients – ENTO in the induction setting for a defined duration of therapy and LANRA for potential treatment to progression," said Jorge DiMartino, M.D., Ph.D., chief medical officer and executive vice president, clinical development. "During today's event, we also look forward to outlining our development strategy for our CDK9 inhibitor KB-0742 and sharing recent preclinical data that highlight the drug's unique properties and potential anti-tumor activity in MYC-dependent cancers that develop in the breast, lungs, stomach and esophagus and in other transcriptionally addicted tumors like sarcoma and chordoma."

Select R&D Day Highlights

Unveils SYK Inhibitor Portfolio Development Strategy
Kronos Bio will unveil the development strategy for the company's SYK inhibitor portfolio comprised of differentiated clinical-stage inhibitors ENTO and LANRA. The strategy will leverage the unique pharmacological properties of each inhibitor to expand the potential impact of SYK inhibition in AML beyond patients who are newly diagnosed with NPM1-mutated AML and eligible for intensive induction chemotherapy.

The company's SYK inhibitor portfolio, in combination with standard of care backbone regimens, could ultimately address both fit and unfit newly diagnosed AML patients with NPM1 and/or FLT3 mutations. In addition, rational combinations of SYK inhibitors with other targeted agents in the relapsed/refractory setting may eventually provide new treatment options for patients with genetically defined subtypes of AML. Specifically, the company plans to initiate the following trials:

- Mid-2021 – Registrational Phase 3 trial for ENTO in patients who are newly diagnosed with NPM1-mutated AML and eligible for intensive induction chemotherapy
- Late 2021 – Phase 1/2 trial for LANRA in combination with gilteritinib in patients with relapsed/refractory FLT3-mutated AML
- Early 2022 – Phase 1/2 trial for LANRA in combination with venetoclax/azacitidine in patients with newly diagnosed NPM1-mutated and/or FLT3-mutated AML who are older than 75 years old or are not eligible for intensive induction chemotherapy

The company's development strategy seeks to maximize the impact of these complementary investigational therapies, which have the potential to address patients with mutations present in more than two-thirds of AML.

Identifies KB-0742 Potential Target Indications Based on Additional Preclinical Data
The company will outline potential target indications for KB-0742, a highly selective, orally bioavailable CDK9 inhibitor in development to treat MYC-dependent, including MYC-amplified, solid tumors and other transcriptionally addicted cancers, based on recent preclinical data demonstrating activity in several tumor types. These data build upon research presented at the 2021 American Association for Cancer Research Annual Meeting that showed CDK9 inhibition on an intermittent dosing schedule resulted in sustained inhibition of tumor growth in multiple cancers.

The company plans to share initial safety, pharmacokinetic (PK) and pharmacodynamic (PD) data from dose escalation cohorts of the Phase 1/2 clinical trial in the fourth quarter of 2021. Following these data, which will be used to establish a recommended dose and schedule, the company plans to initiate testing in expansion cohorts to assess KB-0742's anti-tumor activity in non-small cell lung cancer, small cell lung cancer, triple-negative breast cancer, gastric/gastroesophageal cancer and in other transcriptionally addicted tumors such as sarcoma and chordoma.

Highlights Unique Capabilities of Discovery Product Engine
Today, Kronos Bio will highlight the unique aspects of its product engine that support the mapping of the transcriptional regulatory networks that drive tumor subtypes and response to treatment, which is critical to discovery efforts. The company will also explain how its small molecule microarray (SMM) screening platform, a key component of its product engine, allows for the identification of highly selective compounds, and will discuss how continuous optimization of the SMM platform for throughput and quality results in a versatile product engine that may allow for the targeting of transcription factors using multiple modalities.

Virtual R&D Day Agenda
The following topics and speakers will be featured at Kronos Bio's Virtual R&D Day (all times are Eastern Time):

1:00 – 1:10 p.m.
Welcome and Introduction
Norbert Bischofberger, Ph.D., President and CEO

1:10 – 1:30 p.m.
Acute Myeloid Leukemia in 2021
Eytan M. Stein, M.D., Director, Program for Drug Development in Leukemia, Leukemia Service, Memorial Sloan Kettering Cancer Center

1:30 – 2:00 p.m.
SYK Inhibition: An opportunity to address mutations present in more than 2/3 of AML
Jorge DiMartino, M.D., Ph.D., Chief Medical Officer and EVP, Clinical Development
Yasir Al-Wakeel, BM BCh, Chief Financial Officer and Head of Corporate Development

2:00 – 2:20 p.m.
Q&A Session #1

2:20 – 2:30 p.m.
Break

2:30 – 3:00 p.m.
CDK9 Inhibition: An opportunity to target the master regulator MYC
Jorge DiMartino

3:00 – 3:30 p.m.
Discovery Pipeline: Maximizing the value of our platform
Charles Lin, Ph.D., SVP, Biology
Christopher Dinsmore, Ph.D., Chief Scientific Officer

3:30 – 3:50 p.m.
Q&A Session #2

3:50 – 4:00 p.m.
Summary and Close
Yasir Al-Wakeel

Virtual R&D Day Webcast Information
The live webcast will begin at 1:00 p.m. ET and conclude at approximately 4:00 p.m. ET. The webcast is accessible from the Investors & Media section of the company's website at www.kronosbio.com. A replay of the event will be available for a limited time on Kronos Bio's website.

About Acute Myeloid Leukemia (AML)
Acute myeloid leukemia (AML) primarily affects adults and is one of the most difficult-to-treat blood cancers. AML starts in the bone marrow and can quickly lead to death as a result of bone marrow failure. Approximately 20,000 Americans are diagnosed with AML each year,[1] with the NPM1 genetic mutation found in approximately 30% of cases.[2] Relapse in AML is common,[3] and despite available treatments, nearly 11,000 Americans will die from the disease each year.[1]

About Entospletinib (ENTO)
Kronos Bio is developing ENTO for the treatment of patients who are newly diagnosed with NPM1-mutated acute myeloid leukemia (AML) and eligible for intensive induction chemotherapy. ENTO is a selective inhibitor targeting spleen tyrosine kinase (SYK), a critical node in a dysregulated transcription regulatory network within AML defined by persistent high expression of the transcription factors HOXA9 and MEIS1 (HOX/MEIS).[4] Multiple AML driver mutations, including NPM1 and MLL gene rearrangements, have been associated with elevation of HOX/MEIS.[5,6] ENTO has been investigated in more than 700 patients with a variety of hematologic malignancies, including AML, with clinical results observed in AML patients with NPM1 and FLT3 mutations and MLL rearrangements that support further development of the therapy.[6,7]

About Lanraplenib (LANRA)
Kronos Bio is developing LANRA, a next-generation selective inhibitor targeting spleen tyrosine kinase (SYK), for the treatment of patients with orelapsed/refractory FLT3-mutated acute myeloid leukemia (AML) and patients newly diagnosed with NPM1-mutated and/or FLT3-mutated AML wh are older than 75 years old or are not eligible for intensive induction chemotherapy. LANRA has been investigated in more than 250 patients with autoimmune diseases. In preclinical studies, LANRA was shown to have anti-leukemic activity against NPM1-mutated and FLT3-mutated AML samples. Two Phase 1/2 clinical trials for LANRA in AML are scheduled to begin in late 2021 and early 2022.

About KB-0742
KB-0742 is a highly selective, orally bioavailable inhibitor of cyclin dependent kinase 9 (CDK9) in development for the treatment of MYC-dependent, including MYC-amplified, solid tumors. CDK9 is a global regulator of transcription and plays an essential role in both the expression and function of MYC, a well-characterized transcription factor and a long-recognized driver of cancer that is amplified in approximately 30% of solid tumors, including those affecting the lungs, ovaries, esophagus, breast, stomach, pancreas and liver.[8] KB-0742 was generated and optimized from a compound that was identified using the company's proprietary small molecule microarray (SMM) screening platform.

About the Small Molecule Microarray (SMM) Screening Platform
Kronos Bio leverages its SMM screening platform to conduct high-throughput screens against traditionally undruggable target proteins, in particular transcription factors. The SMM platform directly addresses the historical challenges of targeting transcription factors by screening in conditions that preserve their associated context-dependent structures and multi-protein complexes. Using the company's library of approximately 240,000 compounds in microarray format on slides, Kronos Bio screens for small molecule binders of the target transcription factor in context-relevant tumor nuclear lysates. Hits derived from SMM screening have the potential to act through a variety of mechanisms against various members of a transcription factor's complex and, as such, hits are characterized for their ability to selectively modulate an oncogenic transcription factor's activity as important criteria for further lead selection and optimization.

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 is developing a portfolio of spleen tyrosine kinase (SYK) inhibitors, entospletinib (ENTO) and lanraplenib (LANRA), for the treatment of NPM1-mutated and FLT3-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-dependent 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.

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 "progress," "expected," "look forward," "unveil," "proceed," "assess," "plans," "initiate," "developed," "provide," "planned," "expectations" "anticipated," 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 plans to conduct a registrational Phase 3 trial of ENTO in frontline fit NPM1-mutated AML, and the timing thereof; Kronos Bio's plans to conduct a Phase 1/2 trial for LANRA in relapsed/refractory FLT3-mutated AML in combination with gilteritinib, and the timing thereof; Kronos Bio's plans to conduct a Phase 1/2 trial for LANRA in frontline unfit NPM1-mutated and/or FLT3-mutated AML in combination with venetoclax/azacitidine, and the timing thereof; the timing of the initial safety, pharmacokinetic (PK) and pharmacodynamic (PD) data from dose escalation cohorts of Kronos Bio's Phase 1/2 clinical trial of KB-0742; potential target indications for KB-0742; Kronos Bio's plans to initiate testing in expansion cohorts to assess KB-0742's anti-tumor activity in small cell lung cancer, non-small cell lung cancer, triple-negative breast cancer, gastric/gastroesophageal cancer and transcriptionally addicted tumors such as sarcoma and chordoma; 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 complete the current and planned clinical trials of ENTO, LANRA and KB-0742 on the timelines expected, if at all, including due to risks associated with the COVID-19 pandemic and 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; 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 March 31, 2021 filed with the SEC on May 11, 2021. 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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