Kura Oncology Announces FDA Clearance of Investigational New Drug Application for Menin-MLL Inhibitor KO-539

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– KO-539 is a potent, selective small molecule inhibitor of the menin-MLL interaction –

– Robust anti-tumor activity observed in mixed lineage leukemias rearranged and oncogenic driver mutations in genes such as NPM1 –

– Phase 1 clinical trial in relapsed or refractory AML expected to initiate next quarter –

SAN DIEGO, March 05, 2019 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company focused on the development of precision medicines for oncology, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's investigational new drug (IND) application for KO-539, a potent and selective small molecule inhibitor of the menin-mixed lineage leukemia (menin-MLL) protein-protein interaction. The Company anticipates initiating a Phase 1 clinical trial of KO-539 in relapsed or refractory acute myeloid leukemia (AML) in the second quarter of 2019.

"Despite recent advances in the treatment of AML, genetically defined subsets of acute leukemias such as MLL-rearrangements and NPM1 mutations remain areas of high unmet need," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "Our data suggest that KO-539 drives robust and persistent responses in these preclinical models by induction of differentiation in AML blasts, a mechanism that is distinct from and potentially complementary to existing therapies. We are very encouraged by these preliminary results, and we look forward to beginning clinical testing of KO-539 next quarter."

MLL-rearranged leukemias are characterized by chromosomal translocations of the MLL gene that are primarily found in patients with AML and acute lymphoblastic leukemia (ALL), the most common type of cancer in children. These translocations form oncogenes encoding MLL fusion proteins, which play a causative role in the onset, development and progression of MLL-rearranged leukemias.

The target genes of the MLL fusion proteins are also found to be overexpressed in a broader subset of AMLs characterized by oncogenic driver mutations in genes such as NPM1. These mutations also appear to be dependent on the interaction between menin and MLL, suggesting that the menin-MLL complex is a central node in epigenetic dysregulation driven by distinct oncogenic driver mutations known to be important in AML and other hematologic malignancies.

In preclinical studies, KO-539 has demonstrated potent and selective inhibition of the proliferation of MLL-rearranged leukemia cell lines. Kura has also generated preclinical data showing robust and durable efficacy in multiple *in vivo* models of AML characterized by MLL-rearrangements or oncogenic driver mutations in genes such as NPM1.

About Kura Oncology

Kura Oncology is a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer. The Company's pipeline consists of small molecule drug candidates that target cancer signaling pathways where there is a strong scientific and clinical rationale to improve outcomes by identifying those patients most likely to benefit from treatment. Kura's lead drug candidate is tipifarnib, a farnesyl transferase inhibitor, for which the Company has initiated a registration-directed trial of tipifarnib in recurrent or metastatic patients with HRAS mutant HNSCC. In addition, tipifarnib is being evaluated in multiple other Phase 2 clinical trials in solid tumor and hematologic indications. Kura's pipeline also includes KO-947, an ERK inhibitor, currently in a Phase 1 dose-escalation trial, and KO-539, a menin-MLL inhibitor, which is anticipated to enter into a Phase 1 clinical trial in the second quarter of 2019. For additional information about Kura, please visit the Company's website at www.kuraoncology.com.

Forward-Looking Statements

This news release contains certain forward-looking statements that involve risks and uncertainties that could cause actual results to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Such forward-looking statements include statements regarding, among other things, the efficacy, safety and therapeutic potential of Kura's product candidate KO-539, and progress and expected timing of Kura's drug development programs and clinical trials. Factors that may cause actual results to differ materially include the risk that compounds that appeared promising in early research or clinical trials do not demonstrate safety and/or efficacy in later preclinical studies or clinical trials, the risk that Kura may not obtain approval to market its product candidates, uncertainties associated with performing clinical trials, regulatory filings and applications, risks associated with reliance on third parties to successfully conduct clinical trials, the risks associated with reliance on outside financing to meet capital requirements, and other risks associated with the process of discovering, developing and commercializing drugs that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such drugs. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "promise," "potential," "expects," "plans," "anticipates," "intends," "continues," "designed," "goal," or the negative of those words or other comparable words to be uncertain and forward-looking. For a further list and description of the risks and uncertainties the Company faces, please refer to the Company's periodic and other filings with the Securities and Exchange Commission, which are available at www.sec.gov. Such forward-looking statements are current only as of the date they are made, and Kura assumes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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