Kura Oncology Doses First Patient in Phase 1 Clinical Trial of Menin-MLL Inhibitor KO-539 in Acute Myeloid Leukemia

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– KO-539 is a first-in-class small molecule inhibitor of the menin-MLL interaction –

– First-in-human trial to determine MTD, expand to genetic subgroups such as NPM1 –

SAN DIEGO, Sept. 16, 2019 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company focused on the development of precision medicines for the treatment of cancer, today announced that the first patient has been dosed in a Phase 1 clinical trial of KO-539, the Company's first-in-class inhibitor of the menin-mixed lineage leukemia (menin-MLL) interaction, in patients with relapsed or refractory acute myeloid leukemia (AML).

"We believe KO-539 represents a differentiated approach to the treatment of patients with AML," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "Our preclinical data for KO-539 support the potential for potent, anti-tumor activity in multiple, genetically defined subsets such as tumors with MLL fusions and rearrangements and NPM1 mutations. With the initiation of this trial, Kura now has three wholly-owned, clinical-stage oncology assets, along with the financial resources to advance each program through important inflection points."

This Phase 1, open-label, dose-escalation study is designed to determine the maximum tolerated dose (MTD) of KO-539 in patients with relapsed or refractory AML. KO-539 will be administered as a once daily oral dose in 28-continuous-day cycles. Upon completion of the dose-escalation portion of the trial, expansion cohorts are planned to further asses the safety and activity of KO-539 in specific genetic subgroups, such as NPM1. Additional information about the Phase 1 trial of KO-539 can be found at ClinicalTrials.gov using the identifier NCT04067336.

In July 2019, the U.S. Food and Drug Administration granted Orphan Drug Designation to KO-539 for the treatment of AML, recognizing the potential for KO-539 to address a population of patients with high unmet need.

About KO-539

KO-539 is a potent and selective small molecule inhibitor of the menin-MLL protein-protein interaction. MLL-rearranged leukemias are characterized by chromosomal translocations of the KMT2A gene that are primarily found in patients with AML and acute lymphoblastic leukemia (ALL). 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 anti-tumor activity 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 is conducting a registration-directed trial 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, and KO-539, a menin-MLL inhibitor, both of which are currently in Phase 1 dose-escalation trials. 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, the progress and expected timing of Kura's drug development programs and clinical trials and the potential benefits of Orphan Drug Designation. 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, risks that the actual benefits of Orphan Drug Designation will not be as expected 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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