Kura Oncology Announces FDA Clearance of IND Application for Menin Inhibitor Ziftomenib in Advanced Gastrointestinal Stromal Tumors (GIST)

August 8, 2024

– Preclinical data suggest combination of ziftomenib and imatinib has potential to resensitize patients to imatinib and induce durable responses –

– Proof-of-concept study evaluating ziftomenib and imatinib in patients with advanced GIST to begin in 1H 2025 –

SAN DIEGO, Aug. 08, 2024 (GLOBE NEWSWIRE) -- Kura Oncology, Inc. (Nasdaq: KURA), a clinical-stage biopharmaceutical company committed to realizing the promise of precision medicines for the treatment of cancer, today announced clearance by the U.S. Food and Drug Administration (FDA) of the Investigational New Drug (IND) application for ziftomenib, the Company's potent and selective menin inhibitor, for the treatment of advanced gastrointestinal stromal tumors (GIST). The Company plans to initiate a Phase 1 first-in-human study of ziftomenib in combination with imatinib, a targeted therapy approved for the treatment of GIST, in early 2025.

"This important milestone represents the first IND clearance of a menin inhibitor to treat GIST, a solid tumor indication with limited treatment options for patients with advanced disease," said Troy Wilson, Ph.D., J.D., President and Chief Executive Officer of Kura Oncology. "Although imatinib is utilized in frontline GIST patients, many eventually develop resistance. Our preclinical data suggest ziftomenib has potential to resensitize patients to imatinib and induce deep, durable responses. We look forward to presenting the preclinical data for the combination at an upcoming scientific meeting and initiating a proof-of-concept clinical study early next year."

GIST is the most common form of sarcoma, characterized as KIT-dependent solid tumors. KIT inhibitors are associated with favorable outcomes for patients with GIST, and imatinib is the standard of care in this patient population. For patients who progress on imatinib, subsequent treatment options include other KIT inhibitors; however, these options are limited by moderate efficacy and challenging tolerability. The menin-MLL complex regulates KIT expression in GIST cells, and menin inhibitors display additive therapeutic activity with imatinib in imatinib-sensitive GIST models[1]. Preclinical data in imatinib-resistant PDX models suggest that ziftomenib in combination with imatinib has the potential to resensitize patients to imatinib and induce durable responses. Kura plans to initiate a proof-of-concept study evaluating ziftomenib in combination with imatinib in patients with advanced GIST after imatinib failure.

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. Ziftomenib, a once-daily, oral drug candidate targeting the menin-KMT2A protein-protein interaction, has received Breakthrough Therapy Designation for the treatment of relapsed/refractory (R/R) NPM1-mutant acute myeloid leukemia (AML). Kura has completed enrollment in a Phase 2 registration-directed trial of ziftomenib in R/R NPM1-mutant AML (KOMET-001). The Company is also conducting a series of clinical trials to evaluate ziftomenib in combination with current standards of care in newly diagnosed and R/R NPM1-mutant and KMT2A-rearranged AML. Tipifarnib, a potent and selective farnesyl transferase inhibitor (FTI), is currently in a Phase 1/2 trial in combination with alpelisib for patients with PIK3CA-dependent head and neck squamous cell carcinoma (KURRENT-HN). Kura is also evaluating KO-2806, a next-generation FTI, in a Phase 1 dose-escalation trial as a monotherapy and in combination with targeted therapies (FIT-001). For additional information, please visit Kura's website at www.kuraoncology.com and follow us on X and LinkedIn.

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 ziftomenib, potential benefits of combining ziftomenib with appropriate standards of care, and progress and expected timing of the ziftomenib program 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, applications and other interactions with regulatory bodies, 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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[1] Hemming ML et al., *Cancer Discov*. 2022;12:1804-1823.

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