Kura Oncology's Menin Inhibitor Ziftomenib Selected for The Leukemia & Lymphoma Society's Pediatric Acute Leukemia (PedAL) Master Clinical Trial

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SAN DIEGO, Dec. 08, 2023 (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, and The Leukemia & Lymphoma Society (LLS), the largest private funder of blood cancer research, today announced a clinical collaboration to evaluate Kura's menin inhibitor, ziftomenib, in combination with chemotherapy in pediatric patients with relapsed/refractory KMT2A-rearranged, NUP98-rearranged or NPM1-mutant acute leukemia.

"We are honored to be designated for the PedAL initiative, marking Kura's continued development of ziftomenib for the treatment of acute leukemias," said Mollie Leoni, M.D., Executive Vice President, Clinical Development. "Kura remains committed to developing new treatment options across the continuum of care, including for pediatric patients with acute leukemias where poor outcomes and significant unmet medical need remain. We are proud to collaborate with an exceptional organization such as LLS, which recognizes the importance of expanding patient populations beyond adults to provide effective therapies to infants and children with blood cancers."

In partnership with the PedAL Initiative, LLS will serve as the coordinating sponsor in North America and the Princess Máxima Center for Pediatric Oncology in Utrecht, the Netherlands, will serve as the coordinating sponsor in Europe. PedAL is a pioneering global master clinical trial for **Ped**iatric **A**cute **L**eukemia, founded and led by LLS, which aims to advance more effective, safer treatments with fewer long-term side effects, for children with blood cancer.

"We developed PedAL as part of LLS's Dare to Dream Project to fundamentally change how children with acute leukemia are treated and to provide a clinical trial framework that would help innovative companies like Kura accelerate research into precision treatments for pediatric patients," said Gwen Nichols, M.D., Chief Medical Officer, The Leukemia & Lymphoma Society. "For too long, progress for children with cancer has lagged behind; this collaboration with Kura is a major step in the right direction."

Under the terms of the agreement, LLS and the Princess Máxima Center will sponsor the Phase 1 study of ziftomenib in pediatric patients with acute leukemias. Kura will supply LLS and the Princess Máxima Center with ziftomenib for the study.

About Ziftomenib

Ziftomenib is a novel, once-daily, oral investigational drug candidate targeting the menin-KMT2A/MLL protein-protein interaction for treatment of genetically defined AML patients with high unmet need. In the KOMET-001 Phase 1 study, ziftomenib demonstrated an encouraging safety profile and tolerability with reported events most often consistent with features and manifestations of underlying disease. Clinical activity of ziftomenib as a monotherapy was optimal at the 600 mg daily dose and a 35% complete remission rate was observed in 20 patients with NPM1-mutant AML treated at the recommended Phase 2 dose (600 mg). Ziftomenib has received Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of AML. Additional information about clinical trials for ziftomenib can be found at kuraoncology.com/clinical-trials/#ziftomenib.

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 is a once-daily, oral drug candidate targeting the menin-KMT2A protein-protein interaction for the treatment of genetically defined acute myeloid leukemia (AML) patients with high unmet need. Kura is currently enrolling patients in a Phase 2 registration-directed trial of ziftomenib in NPM1-mutant relapsed or refractory AML (KOMET-001). The Company is also conducting a series of studies to evaluate ziftomenib in combination with current standards of care, beginning with venetoclax and azacitidine and 7+3 in NPM1-mutant and KMT2A-rearranged newly diagnosed and relapsed/refractory AML (KOMET-007). 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 adagrasib in $KRAS^{G12C}$-mutated non-small cell lung cancer and cabozantinib in clear cell renal cell carcinoma (FIT-001). For additional information, please visit Kura's website at www.kuraoncology.com and follow us on X and LinkedIn.

About PedAL Master Clinical Trial

As part of LLS's Dare to Dream Project, the Pediatric Acute Leukemia Master Trial (PedAL) is the first-of-its-kind global master clinical trial for pediatric acute leukemia patients that will fundamentally change how children are treated.

Prior to enrolling in therapeutic trials, patients enroll in the PedAL Screening Trial (APAL2020SC) to identify the unique tumor biology of each child's cancer and help them to match with the most promising treatment. The Screening Trial is currently open at multiple sites in the United States, Canada, Australia, and New Zealand; a companion Registry (EuPAL 2021 Registry) is open in Germany and more countries will open soon. At this time, one PedAL therapeutic trial is open and actively enrolling patients in the U.S., Canada, Australia, New Zealand, and Europe, with more therapeutic trials planned for global execution. To learn more about PedAL, visit lls.org/dare-to-dream.

About The Leukemia & Lymphoma Society (LLS)

The Leukemia & Lymphoma Society® (LLS) is the global leader in the fight against blood cancer. The LLS mission: Cure leukemia, lymphoma,

Hodgkin's disease, and myeloma, and improve the quality of life of patients and their families. LLS funds lifesaving blood cancer research around the world, provides free information and support services, and is the voice for all blood cancer patients seeking access to quality, affordable, coordinated care.

Founded in 1949 and headquartered in Rye Brook, NY, LLS has regions throughout the United States and Canada. To learn more, visit www.LLS.org. Patients should contact the Information Resource Center at (800) 955-4572, Monday through Friday, 9 a.m. to 9 p.m. ET.

LLS is the only organization featured in the nonprofit category on both Fast Company's 2022 Brands That Matter list and the 2023 Best Workplaces for Innovators list. LLS stands out among brands around the world for its relevancy, cultural impact, ingenuity, and mission impact.

For additional information, visit lls.org/lls-newsnetwork. Follow us on Facebook, X, Instagram and LinkedIn.

About the Princess Máxima Center for pediatric oncology

When a child is seriously ill from cancer, only one thing matters: a cure.

Every year, 600 children in the Netherlands are diagnosed with cancer. Sadly, one in four of these children dies. That is why in the Princess Máxima Center for pediatric oncology, we work together with passion and without limits every day to improve the survival rate and quality of life of children with cancer. Now, and in the long term. Because children have their whole lives ahead of them.

The Princess Máxima Center is no ordinary hospital, but a research hospital. All children with cancer in the Netherlands are treated here, and it's where all research into childhood cancer in the country takes place. This makes the Princess Máxima Center the largest pediatric cancer center in Europe. More than 900 healthcare professionals and 450 scientists work closely with Dutch and international hospitals to find better treatments and new perspectives for a cure.

In this way, we offer children today the best possible care, and we take important steps to improve survival for children who cannot not yet be cured.

Kura's 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.

Kura Contacts

Investors:
Pete De Spain
Executive Vice President, Investor Relations &
Corporate Communications
(858) 500-8833
pete@kuraoncology.com

Media:
Alexandra Weingarten
Senior Manager, Corporate Communications
(858) 500-8822
alexandra@kuraoncology.com

LLS Contacts

Media:
Ryan McDonald
Senior Manager, Medical & Science Communications
Ryan.McDonald@lls.org

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