Curis Announces Dosing of First Patient in Phase I Clinical Trial of Dual PI3 Kinase and HDAC Inhibitor CUDC-907

Curis Earns $350,000 in Milestone Payments From The Leukemia & Lymphoma Society

LEXINGTON, Mass., Jan. 24, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), a drug development company seeking to develop next generation targeted small molecule drug candidates for cancer treatment, today announced that the first patient has been treated in a Phase I clinical study of CUDC-907 in patients with relapsed or refractory lymphoma or multiple myeloma. CUDC-907 is an orally-administered first-in-class small molecule drug candidate that has been designed as a dual inhibitor of phosphatidylinositol-3-kinase (PI3K) and histone deacetylase (HDAC). As a result of this clinical advance, Curis is entitled to receive an additional $350,000 in milestone payments under the terms of its agreement with The Leukemia and Lymphoma Society (LLS).

"We're very pleased to announce the initiation of the CUDC-907 Phase I clinical study in patients with advanced hematological cancers," said Dan Passeri, Curis' President and Chief Executive Officer. "The synergistic effects of targeting PI3K and HDAC with CUDC-907 have shown very potent antitumor activity in preclinical models of lymphoma and multiple myeloma. We are hopeful that CUDC-907 will demonstrate an adequate safety profile and also provide clinical activity in this study population. We look forward to seeking to advance this important molecule through this Phase I dose escalation study and further clinical trials."

"LLS is pleased that Curis has met this significant milestone," said Richard Winneker, Ph.D, LLS senior vice president of research. "Initiating this first human clinical trial for this drug candidate is a major advance, and we are hopeful that this therapy could yield promising outcomes for patients with lymphomas and multiple myeloma, who are often in critical need of new treatment options."

This clinical trial is designed as a standard dose escalation study in which CUDC-907 will be orally administered to patients with relapsed or refractory lymphoma or multiple myeloma at up to four study centers in the United States. The primary objectives of the study are to determine the maximum tolerated dose and recommended oral dose of CUDC-907 for Phase II study. The secondary objectives of this study are to assess safety and tolerability, to assess pharmacokinetics, to evaluate biomarker activity and to assess preliminary anti-cancer activity of CUDC-907 in this patient population.

In the absence of dose limiting toxicity, each patient will receive oral CUDC-907 once daily for a minimum of 21 days of continuous daily dosing (1 cycle), and may continue to receive additional cycles of study treatment until disease progression or other treatment discontinuation criteria are met. Additional details about this study can be found on clinicaltrials.gov (NCT01742988).

About CUDC-907

CUDC-907 is a dual inhibitor of the Class I PI3K and Class I and II HDAC subtypes, the combination of which Curis scientists believe has synergistic interaction against cancer cells and their microenvironment. In preclinical studies, CUDC-907 has demonstrated the ability to suppress multiple nodes of survival and proliferation. In addition, preclinical data have shown that CUDC-907 inhibits compensatory pathways often utilized in cancer cells during the emergence of resistance to standard of care agents and induces apoptosis in treated cancer cells.

CUDC-907 exhibits anti-proliferation activity against a broad range of cancer cell types in *in vitro* studies, including cell lines that exhibit reduced sensitivity to single-target PI3K inhibitors. CUDC-907's anti-proliferation activity has been demonstrated to be much more potent than that of leading PI3K inhibitors in development. CUDC-907 also inhibits tumor growth in preclinical xenograft models of blood cancers as well as solid tumors with K-RAS mutations that exhibit reduced sensitivity to known PI3K inhibitors, indicating that this compound may have the potential for broader activity than other leading PI3K inhibitors currently in clinical development.

About the LLS Agreement

Under the agreement between Curis and LLS, LLS has agreed to fund approximately 50% of the direct costs of the development of CUDC-907, up to $4 million, of which Curis received $1.1 million in funding to date. As noted above, Curis has initiated a Phase I dose escalation clinical trial in patients with relapsed or refractory lymphomas or multiple myeloma. Provided that the Phase I study is successful, the agreement also provides for LLS to support Curis' subsequent Phase Ib or Phase IIa study in one or more specific indications as well as Curis' ongoing investigation of biomarkers for CUDC-907 in these diseases.

About TheLeukemia & Lymphoma Society

The Leukemia & Lymphoma Society ® (LLS) is the world's largest voluntary health agency dedicated to 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 and provides free information and support services. Founded in 1949 and headquartered in White Plains, NY, LLS has chapters throughout the United States and Canada. To learn more, visit www.LLS.org or contact the Information Resource Center at (800) 955-4572, Monday through Friday, 9 a.m. to 6 p.m. ET. www.lls.org.

About Curis, Inc.

Curis is a drug development company seeking to develop and commercialize next generation targeted small molecule drug candidates for cancer treatment. Erivedge® is the first and only FDA-approved medicine for the treatment of advanced basal cell carcinoma and is being commercialized and was developed by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech. Curis is also leveraging its experience in targeting signaling pathways to develop proprietary targeted cancer programs, including CUDC-427, a small molecule IAP inhibitor, and CUDC-907, a dual PI3K and HDAC inhibitor. For more information, visit Curis' website at www.curis.com.

The Curis, Inc. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=11347

Curis Cautionary Statement: *This press release contains forward-looking statements within the meaning of the Private Securities Litigation*

Reform Act of 1995, including without limitation statements regarding Curis' expectations regarding the potential safety profile and clinical benefits of CUDC-907, the Company's goals for advancing the molecule through clinical studies and the Company's expectation that LLS will support the Company's subsequent preclinical studies and clinical trials. Forward-looking statements used in this press release may contain the words "believes," "expects," "anticipates," "plans," "seeks," "estimates," "assumes," "will," "may," "could" or similar expressions. These forward-looking statements are not guarantees of future performance and involve risks, uncertainties, assumptions and other important factors that may cause actual results to be materially different from those indicated by such forward-looking statements. For example, Curis (i) may not be able to successfully enroll patients in its Phase I clinical trial of CUDC-907, (ii) may experience delays, setbacks and other failures in its planned clinical development of CUDC-907, including negative, inconsistent or inconclusive results, and/or results that fail to achieve the primary or secondary objectives of the trial, (iii) may encounter manufacturing delays or difficulties and (iv) may be required by the FDA or institutional review boards to hold, delay, suspend or terminate such trial. Moreover, Curis may not be able to maintain its collaboration agreement with LLS on terms that are favorable to Curis, or at all. Curis also faces other important risks relating to its business, operations, financial condition and future prospects generally that are discussed in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 and other filings that it periodically makes with the Securities and Exchange Commission.

In addition, any forward-looking statements represent the views of Curis only as of today and should not be relied upon as representing Curis' views as of any subsequent date. Curis disclaims any intention or obligation to update any of the forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise.

CONTACT:
Michael P. Gray

Chief Financial and Chief Operating Officer

Curis, Inc.

617-503-6632

mgray@curis.com

Andrea Greif

Director of Public Relations

The Leukemia & Lymphoma Society

(914) 821-8958

andrea.greif@lls.org
