Curis Achieves CUDC-907 Milestones Under Its Agreement With The Leukemia & Lymphoma Society

IND Filed to Begin Phase I Clinical Testing of CUDC-907

LEXINGTON, Mass., Oct. 18, 2012 (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 it has achieved the first two development milestones under its agreement with The Leukemia & Lymphoma Society (LLS) for the development of CUDC-907, a first-in-class orally-administered small molecule drug candidate inhibitor of phosphatidylinositol-3-kinase (PI3K) and histone deacetylase (HDAC). These milestones include a preclinical development objective, as well as Curis' recent filing of an Investigational New Drug (IND) application to begin Phase I clinical testing of CUDC-907 in patients. As a result, Curis will receive $750,000 in milestone payments under the terms of its agreement with LLS.

"The completion of CUDC-907's preclinical testing and subsequent IND filing is a significant milestone in the development of this important molecule, and we look forward to initiating a Phase I clinical trial in patients with relapsed or refractory lymphomas or multiple myeloma in early 2013," said Dan Passeri, Curis' President and Chief Executive Officer. "In preclinical studies, CUDC-907 has demonstrated very potent anti-proliferation activity, and we believe that this approach of disrupting multiple signaling networks with a single-agent drug candidate holds a great deal of promise for patients with advanced cancers. The upcoming Phase I dose escalation study will be extremely important for selecting a dose of CUDC-907 given orally to this specific patient population to be used for further efficacy testing. "

"We are pleased that Curis' research and development team has successfully completed the preclinical work required to advance CUDC-907 towards clinical testing in patients with lymphomas and multiple myeloma, said Richard Winneker, LLS's Senior Vice President of Research. "These patients are often in critical need of new treatment options and LLS's Therapy Acceleration Program (TAP) has provided important capital to companies like Curis to continue advancing novel drug candidates for the treatment of blood cancers."

About the CUDC-907 Phase I Dose Escalation Trial

The Phase I 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 trial are to determine the maximum tolerated dose (MTD) and recommended Phase II dose of oral CUDC-907. 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.

About CUDC-907

CUDC-907 is a potent 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. 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 broader activity than other leading PI3K inhibitors currently in clinical development.

About the LLS Agreement

Under the agreement, LLS will fund approximately 50% of the direct costs of the development of CUDC-907, up to $4 million. Curis is currently seeking to advance the molecule into a Phase I dose escalation clinical trial in patients with relapsed or refractory lymphomas or multiple myeloma in early 2013. If this study is successful, LLS has also agreed to support Curis's 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 that is committed to leveraging its innovative signaling pathway drug technologies to seek to create new targeted small molecule drug candidates for cancer. Curis is building upon its previous experiences in targeting signaling pathways, including in the Hedgehog pathway, in its effort to develop proprietary targeted cancer programs. 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 benefits of the oral formulation of CUDC-907. 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 may not be able to successfully enroll patients in this Phase I clinical trial or may otherwise experience delays, setbacks and failures in its clinical development of CUDC-907, and the oral form of CUDC-907 may cause unexpected toxicities.*

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 June 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
