Curis Announces Initiation of a Clinical Trial of CUDC-427 In Advanced Malignancies

Expansion Cohort Primarily to Include Ovarian and Fallopian Tube Cancers

LEXINGTON, Mass., July 25, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused drug development company seeking to develop novel drug candidates for the treatment of human cancers, today announced dosing of the first patient in a Phase 1 dose-escalation study of CUDC-427 that is being conducted using a continuous, twice-daily oral dosing regimen in patients with advanced and refractory solid tumors or lymphoma. This trial builds on the single agent clinical results observed in the initial Phase 1 trial of CUDC-427, which were presented at the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2013. The primary objectives of the current study are to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose of CUDC-427 using a more frequent dosing regimen. Additionally, the trial is designed to enroll up to 12 patients in an expansion cohort, which is expected to primarily include patients with ovarian and fallopian tube cancers. CUDC-427 is an oral, small molecule Smac mimetic drug candidate that selectively antagonizes inhibitor of apoptosis (IAP) proteins in cancer cells, resulting in induction of programmed cell death.

"The encouraging results of the previous Phase 1 trial for CUDC-427, including complete responses in a patient with ovarian cancer and a mucosa-associated lymphoid tissue (MALT) lymphoma patient, strongly support further evaluation of this agent in patients with certain genetic alterations," said Anthony W. Tolcher, M.D., FRCP, Director of Clinical Research at South Texas Accelerated Research Therapeutics (START). "In addition to this trial, we are also conducting additional preclinical studies to further explore potential mechanisms of CUDC-427's activity using ovarian and breast cancer patient-derived xenograft models. The preclinical data in combination with data from the recently initiated study are expected to provide strong rationale for further development of CUDC-427 as a single agent in select malignancies."

"We are excited to investigate CUDC-427 monotherapy using a continuous daily dosing regimen, which we believe has the potential to further enhance its anti-tumor activity as a single agent in difficult to treat cancers," said Ali Fattaey, Curis President and Chief Operating Officer. "Additionally, the expansion phase of this trial will further study CUDC-427's activity in patients with ovarian and fallopian tube cancers, where we expect to investigate CUDC-427 in patients with cancers of different genetic profiles, including patients with known gene mutations."

In addition to this Phase 1 trial, Curis is also planning to initiate clinical studies with CUDC-427 in patients with breast cancer and other malignancies. Curis is currently planning to initiate a clinical study evaluating the use of CUDC-427 in combination with capecitabine to treat HER2-negative breast cancer patients in 2013. The trial will be designed to initially determine the optimal dose of CUDC-427 in combination with the standard capecitabine regimen. In addition, the company also plans to examine CUDC-427 for the treatment of aggressive lymphomas as well as certain indolent lymphomas such as MALT lymphomas.

About the Phase 1 Dose Escalation Trial

This Phase 1, open-label, multicenter study is designed to determine the MTD and recommended Phase 2 dose of oral CUDC-427 administered as a single agent twice-daily on a continuous daily schedule for a 21-day cycle in patients with advanced and refractory solid tumors or lymphomas. The secondary objectives of the study are to assess CUDC-427's safety and tolerability, pharmacokinetics, exploratory biomarkers of activity and preliminary anti-cancer activity. Patients will be dose escalated according to the standard 3+3 design with a starting dose of 400 mg/day (200 mg BID) and escalated at increments of 200 mg/day. Upon determination of MTD or the recommended Phase 2 dose, the trial is designed to enroll up to an additional 12 patients in the expansion cohort of a particular cancer type, primarily ovarian and fallopian tube cancers.

About CUDC-427 (previously referred to as GDC-0917)

CUDC-427 is an oral, synthetic, small molecule that triggers tumor cell apoptosis by selectively antagonizing inhibitor of apoptosis (IAP) proteins, which are frequently over-expressed in cancer cells. CUDC-427 was designed to mimic the endogenous IAP antagonist, second mitochondria-derived activator of caspases/direct IAP-binding protein (Smac/DIABLO) that is released into the cytoplasm in response to pro-apoptotic stimuli and binds to the IAPs.

CUDC-427 has demonstrated single-agent and combination therapy anti-tumor activity in mouse xenograft tumor models when administered orally. IND-enabling safety studies have shown CUDC-427 to be well tolerated when dosed daily by oral administration, potentially enabling sustained target inhibition. In a single-agent Phase 1 clinical trial in patients with advanced malignancies, CUDC-427 demonstrated a favorable safety profile and exhibited anti-tumor activity in some patients when it was administered at once daily dosing regimen with 14 days "on" and 7 days "off" for a 21-day cycle. CUDC-427 was exclusively licensed from Genentech in November 2012.

About Curis, Inc.

Curis is an oncology-focused drug development company seeking to develop novel drug candidates for the treatment of human cancers. Erivedge is the first and only FDA-approved medicine for the treatment of advanced basal cell carcinoma and is being commercialized and developed by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech. Curis is also seeking to further the development of its pipeline of proprietary targeted cancer drug candidates, including CUDC-427, a small molecule antagonist of IAP proteins, and CUDC-907, a dual PI3K and HDAC inhibitor. For more information, visit Curis' website at www.curis.com.

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 for the timing of conducting additional clinical studies with CUDC-427 as well as the potential benefits and safety of this drug candidate. 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 and its collaborators may experience adverse results, delays and/or failures in their drug development programs. Curis' drug candidates, including CUDC-427, are unproven and may cause unexpected toxicities and/or fail to demonstrate sufficient safety and efficacy in clinical trials and may never achieve the requisite regulatory

approval needed for commercialization. Curis will require substantial additional capital to fund the research and development of its drug development programs, and such capital may be difficult to obtain. Curis may not obtain or maintain necessary patent protection for its programs and could become involved in expensive and time consuming patent litigation and interference proceedings. Curis faces substantial competition from other companies developing cancer therapeutics. Unstable market and economic conditions may adversely affect Curis' financial conditions and its ability to access capital to fund the growth of its business. Curis also faces other important risks relating to its business, operations, financial condition and future prospects that are discussed in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 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.

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