Curis Announces CUDC-427 (GDC-0917) Phase I Clinical Data Presented at ASCO 2013 Annual Meeting

LEXINGTON, Mass., June 3, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused company seeking to develop next generation targeted drug candidates for cancer treatment, today announced that Phase I data were presented during an oral session at the American Society of Clinical Oncology's (ASCO) 2013 annual meeting on the Company's clinical candidate CUDC-427 (previously GDC-0917), in patients with refractory cancers. In addition to demonstrating a favorable safety and pharmacokinetic profile, single agent CUDC-427 also showed preliminary signals of clinical activity; including unconfirmed complete responses in 2 patients. CUDC-427 is an oral, small molecule Smac mimetic drug candidate that triggers programmed cell death by selectively antagonizing inhibitor of apoptosis, or IAP, proteins in cancer cells. CUDC-427 was exclusively licensed from Genentech in November 2012, and the results reported were from the Phase I study conducted by Genentech.

"We are pleased with the Phase I study results, which demonstrate CUDC-427's favorable safety, pharmacokinetic and pharmacodynamic profile in patients with advanced malignancies, while also providing clinical benefit as a single agent in certain cancer patients," said Ali Fattaey, Curis President and Chief Operating Officer. "We expect to initiate a mid-stage clinical trial to further assess the efficacy of CUDC-427 in combination with standard chemotherapy in patients with advanced breast cancer in the third quarter of 2013. We are also starting additional studies to further examine single agent activity of CUDC-427 in select cancer patients based on the Phase I clinical observations, which are consistent with CUDC-427's molecular targets and mechanism of action."

"The preclinical and encouraging Phase I study results suggest development strategies that include specific drug combination approaches to treat subsets of cancer patients, as well as novel single agent treatment strategies for specific patient populations based on the underlying nature of the patient's disease," said Anthony W. Tolcher, M.D., FRCP, Director of Clinical Research at South Texas Accelerated Research Therapeutics (START). "For example, we observed unconfirmed complete responses in a patient with ovarian cancer and a MALT lymphoma patient in this study. We are evaluating the correlation between these responses with the underlying genetic profile of the patients' cancer and conducting additional preclinical studies to further explore potential mechanisms of the drug candidate's activity. These analyses will be the basis for further testing of CUDC-427 as a single agent to treat selected cancer patients."

Preclinical studies demonstrated antitumor efficacy of GDC-0917 (CUDC-427) alone or in combination with other anticancer agents including chemotherapy. In October 2010, Genentech initiated an open-labeled, uncontrolled, dose-escalation, Phase I clinical study of GDC-0917 (NCT01226277; IAM4914g) in patients with refractory solid tumors or lymphoma. The study was designed to assess safety, tolerability and pharmacokinetics of daily, oral doses of GDC-0917. The presentation at ASCO focused on results from this Phase I trial, in which oral GDC-0917 was administered once daily for two weeks on and one week off treatment schedule.

Forty two patients were enrolled across 11 cohorts, in which patients received GDC-0917 at doses ranging between 5 mg - 600 mg daily. Unconfirmed complete responses were observed in one ovarian cancer patient and one patient with MALT lymphoma. In addition, a mixed response was observed in one patient with a carcinoma of unknown primary origin and stable disease was observed for greater than three months in four additional patients. GDC-0917 drug levels in patient plasma were dose-proportional with an average half-life of approximately four to eight hours. No apparent drug accumulation was seen at steady state levels. Biomarker changes in the peripheral blood cells (at all dose levels) and in tumor biopsies analyzed (n=2) were consistent with the drug candidate's mechanism of action.

The maximum tolerated dose for GDC-0917 has not been determined, although plasma concentrations of preclinically defined ED90 were reached. Adverse events (AEs) reported as treatment-related that were equal to or greater than Grade 3 in severity in more than one patient were elevated levels of AST and ALT liver enzymes (two patients at 450 and 600 mg dose). AEs that resulted in treatment discontinuation were Grade 3 fatigue, Grade 2 QTc prolongation, Grade 2 drug hypersensitivity, Grade 2 pneumonitis (one patient each), and Grade 3 pruritus/Grade 2 rash.

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

CUDC-427 is an orally bioavailable small molecule that triggers tumor cell apoptosis by selectively antagonizing IAP proteins. 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.

CUDC-427 has demonstrated single-agent and combination therapy anti-tumor activity in mouse xenograft tumor models when administered orally, and IND-enabling safety studies have shown it to be well tolerated when dosed daily by oral administration, potentially enabling sustained target inhibition.

About Curis, Inc.

Curis is an oncology-focused company seeking to develop and commercialize next generation targeted 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 developed by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech. Curis is also developing its pipeline of proprietary targeted cancer drug candidates, including CUDC-427, a small molecule antagonist of IAP proteins; CUDC-907, a dual PI3K and HDAC inhibitor; and CUDC-101, an EGFR/HER2 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 regarding the timing of conducting additional clinical studies with CUDC-427 as well as the potential benefits 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 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. The proceeds of Curis' royalty-secured loan may not be sufficient to fund its near-term capital requirements for advancing programs. 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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