Curis Announces Re-Initiation of Patient Dosing in CUDC-427 Monotherapy Clinical Trial

Expansion Phase to Include Patients With Ovarian Cancer and Certain Hematologic Malignancies

LEXINGTON, Mass., June 5, 2014 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused biotechnology company developing novel drug candidates for the treatment of human cancers, today announced that it has re-initiated dosing in the single-agent clinical trial of CUDC-427 in patients with advanced and/or refractory solid tumors or lymphomas. CUDC-427 is a novel, oral small molecule that is designed to promote cancer cell death by antagonizing inhibitor of apoptosis (IAP) proteins that support survival of cancer cells.

The primary objective of the monotherapy study under the amended protocol is to determine the safety and recommended Phase 2 dose for CUDC-427 when administered orally once daily for two weeks, followed by a one week rest period in 21-day cycles until disease progression or study discontinuation. The study is expected to enroll patients in consecutive cohorts at dose levels of 100 to 300 mg per day. In addition to safety and tolerability measures, the amended protocol is designed to enroll patients in an expansion cohort, which is planned to be limited to patients with ovarian or certain hematologic cancers, including mucosa-associated lymphoid tissue (MALT) lymphoma.

"We are pleased that patients can once again receive CUDC-427 and are looking forward to further investigating this drug candidate's potential as a single agent," said Anthony W. Tolcher, M.D., FRCP, Director of Clinical Research at South Texas Accelerated Research Therapeutics (START). "We will continue to analyze specific genetic alterations and molecular signatures that may render certain patients' cancers more susceptible to CUDC-427's effects."

"We are pleased to have re-opened enrollment on the CUDC-427 monotherapy trial at START and Sarah Cannon Research Institute with risk mitigation measures designed to ensure patient safety," said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. "We continue to believe in CUDC-427's potential as an anti-cancer agent either as a single agent or in combination settings in select cancer types."

"We look forward to building and expanding upon the promising clinical results previously observed with CUDC-427," added Jeffrey Infante, M.D., Director of Drug Development Program at the Sarah Cannon Research Institute (SCRI).

About the Phase 1 Dose Escalation Trial

This Phase 1, open-label, multicenter study is designed to determine the safety and recommended Phase 2 dose of oral CUDC-427 administered once daily as a single agent on a 14 days on/7 days off schedule in 21-day cycles in patients with advanced and/or refractory solid tumors or lymphoma. The secondary objectives of the study are to assess CUDC-427's tolerability, pharmacokinetics, exploratory biomarkers of activity and preliminary anti-cancer activity. Patients are expected to be enrolled in consecutive cohorts according to the standard 3+3 design at once daily dose levels ranging from 100 to 300 mg. Upon determination of the recommended Phase 2 dose, the trial is designed to enroll expansion cohorts with up to 12 more patients with a particular type of cancer. For additional details, please refer to www.clinicaltrials.gov (NCT01908413).

About CUDC-427

CUDC-427 is an oral, small molecule Smac mimetic that is designed to promote cancer cell death by antagonizing inhibitor of apoptosis (IAP) proteins. IAP proteins are a family of functionally and structurally related proteins that promote cancer cell survival by inhibiting programmed cell death, also known as apoptosis, which is a normal process inherent in every cell. Using IAP proteins and other anti-apoptotic factors, cancer cells evade apoptosis in response to a variety of signals, including those provided by anti-cancer agents such as chemotherapy, or naturally occurring inflammatory and immune signals transmitted through members of the tumor necrosis factor (TNF) family. IAP inhibitors such as CUDC-427 are designed to counteract the effects of IAP proteins, thus shifting the balance away from cancer cell survival and allowing apoptosis to proceed.

About Curis, Inc.

Curis is an oncology-focused biotechnology company developing novel drug candidates for the treatment of human cancers. Curis is seeking to further the development of its pipeline of drug candidates, including CUDC-907, a dual histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K) inhibitor, and CUDC-427, a small molecule antagonist of IAP proteins. Curis is also engaged in a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are developing and commercializing Erivedge®, the first and only FDA-approved medicine for the treatment of advanced basal cell carcinoma. Curis' HSP90 inhibitor, Debio 0932 is being studied in patients with advanced lung and kidney cancers by partner Debiopharm. For more information, visit Curis' website at www.curis.com.

Cautionary Note Regarding Forward-Looking Statements:

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' timelines for ongoing and additional clinical studies of CUDC-427, both as a monotherapy and in combination with other chemotherapeutic agents, 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 faces a number of risks inherent in the research and development of novel drugs to treat cancer and may not be able to successfully advance the development of any of its programs, including CUDC-907 and CUDC-427, in the time frames it projects,

if at all. Curis and its collaborators may experience adverse results, delays and/or failures in their drug development programs. Curis' drug candidates, including CUDC-427 and CUDC-907, 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. The FDA could impose restrictions on clinical trials of Curis' drug candidates, which could delay, make more costly or otherwise adversely impact Curis' future development plans. Curis will require substantial additional capital to fund its research and development programs, and such capital may not be available on reasonable terms, or at all. 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. Curis is dependent upon third party collaborations and may not be able to maintain these arrangements on acceptable terms, or at all. Unstable market and economic conditions may adversely affect Curis' financial condition 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 Annual Report on Form 10-Q for the period ended March 31, 2014 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 forward-looking statements after the date of this press release except as may be required by law.

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