Curis Announces Dosing of First Patient in Phase I Clinical Trial of Oral Formulation of CUDC-101

LEXINGTON, Mass., Oct. 2, 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 the first patient has been treated in a Phase I clinical study of an oral formulation of CUDC-101 in patients with advanced and refractory solid tumors. CUDC-101 is a first-in-class small molecule drug candidate that has been designed as an inhibitor of histone deacetylase (HDAC), epidermal growth factor receptor (EGFR) and epidermal growth factor receptor 2 (Her2).

"We are pleased to participate in this trial of an oral formulation of this promising drug candidate," commented Dr. Anthony Tolcher, M.D., FRCP (C), Director of Clinical Research at South Texas Accelerated Research Therapeutics (START) in San Antonio, Texas, where the first patient was treated. Dr. Tolcher was the principal investigator for the Phase I dose escalation study of the intravenous (IV) formulation of CUDC-101. "Preliminary data from prior Phase I clinical studies of the IV formulation of CUDC-101 are intriguing, with CUDC-101 having demonstrated a favorable safety profile as well as initial signs of clinical activity," said Dr. Tolcher.

"The initiation of this Phase I clinical trial of an oral formulation of CUDC-101 is an important milestone for Curis. A successful outcome in this Phase I clinical study could greatly expand the potential for CUDC-101 to be further studied in several cancers, including but not limited to non-small cell lung and gastric cancers, where single pathway targeted agents have demonstrated clinical efficacy," said Dan Passeri, Curis' President and Chief Executive Officer. "We believe that CUDC-101 has potential in a number of additional indications as well, and we also are currently conducting a Phase I dose escalation study of the intravenous (IV) formulation of CUDC-101 in patients with locally advanced head and neck cancers in combination with standard of care radiation therapy and cisplatin."

About the Phase I Dose Escalation Trial

The Phase I clinical trial is designed as a standard dose escalation study in which a tablet form of CUDC-101 will be orally administered to patients with advanced or refractory solid tumors at two study centers in the United States. The primary objectives are to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose of oral CUDC-101 and to assess the bioavailability and pharmacokinetics of orally administered CUDC-101. The secondary objectives of this study are to assess safety and tolerability, to evaluate biomarkers of CUDC-101 activity and to assess preliminary anti-cancer activity.

The bioavailability of oral CUDC-101 will be assessed among patients enrolled in the first 3 dose level cohorts, who will initially receive single, matched IV and oral doses of CUDC-101 prior to initiating oral twice daily study treatment in the dose escalation portion of the study.

In the absence of dose limiting toxicity, each patient will receive oral CUDC-101 twice 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-101

CUDC-101 is designed as a first-in-class therapeutic to simultaneously inhibit HDAC, EGFR and Her2. To date, Curis has completed a Phase I dose escalation clinical trial of the IV formulation of CUDC-101 in 25 patients with advanced, refractory solid tumors and a Phase I expansion trial in which IV CUDC-101 was administered to 46 patients with specific tumor types, including breast, gastric, head and neck, liver and non-small cell lung cancers. The Phase I expansion trial was designed as an open-label study in which patients were treated with CUDC-101 at the MTD, which was determined in the Phase I dose escalation study to be 275 milligrams per meter squared. The primary objectives of this study were to assess the safety and tolerability of CUDC-101 when administered as a one-hour IV infusion on either a five days per week schedule (one week on/one week off) or a three days per week schedule (three weeks on/one week off).

In 2011, Curis initiated a Phase I clinical trial of IV CUDC-101 in patients with intermediate and high-risk locally advanced head and neck cancer, including patients whose tumor is human papillomavirus (HPV) negative or HPV positive and have at least a 10 pack-years smoking history. The primary objectives of this study are to evaluate the safety, tolerability and MTD of CUDC-101 when administered in combination with standard-of-care of radiation therapy and cisplatin.

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-101. 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-101, and the oral tablet form of CUDC-101 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.

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