Curis Announces CUDC-907 Development Program Advancements

Expansion cohorts opened to enroll patients with relapsed/refractory Diffuse Large B-Cell Lymphoma and Multiple Myeloma

Second IND open for Curis to initiate additional clinical study in patients with advanced solid tumors

LEXINGTON, Mass., Oct. 2, 2014 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused biotechnology company developing novel drug candidates for the treatment of human cancers, today announced advances in the development of CUDC-907, its oral, dual inhibitor of histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K) enzymes that is currently under investigation in a first-in-human single agent trial in patients with relapsed/refractory lymphomas or multiple myeloma. Curis has opened expansion cohorts in this ongoing Phase 1 study at the dose of 120 mg administered three times per week (TIW), which was determined to be the maximum tolerated (MTD) dose for this schedule in the dose escalation phase of the trial. The expansion phase of the trial is projected to enroll up to 12 patients each with either relapsed/refractory Diffuse Large B-Cell Lymphoma (DLBCL) or multiple myeloma. The selection of DLBCL and multiple myeloma as lead hematologic indications for further investigation is supported by preclinical data as well as preliminary anti-cancer activity observed in the dose escalation phase of the ongoing trial.

In addition, Curis announced that a second Investigational New Drug (IND) application for CUDC-907 has been accepted by the U.S. Food & Drug Administration and a new study will be initiated under this IND that will enroll patients with advanced solid tumors, including patients with hormone receptor positive breast cancer, among others.

"We are encouraged by the signals of clinical benefit observed in the dose escalation cohorts and are pleased to advance CUDC-907 into the expansion stage of our Phase 1 trial in patients with DLBCL and multiple myeloma," said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. "There remains a substantial need for new therapies to treat patients with relapsed or refractory forms of these cancers. We believe that the next few months will provide important information about the potential benefit of CUDC-907 in these patients."

Dr. Fattaey continued, "Based on CUDC-907's profile, we are also excited to initiate a separate CUDC-907 study in the coming weeks for the treatment of patients with relapsed solid tumors under the new IND. Preclinical studies of CUDC-907 and published data on HDAC and PI3K inhibitors strongly support the investigation of CUDC-907 in advanced solid tumors such as hormone-receptor positive breast cancer."

About the Ongoing Phase 1 Study and Expansion Phase

The dose escalation stage of the trial is designed to assess the safety, tolerability and preliminary anti-cancer activity of multiple doses of CUDC-907 administered at various schedules including continuous once daily (QD), two times per week (BIW), three times per week (TIW), and five days on/two days off (5/2) administration schedules in patients with relapsed/refractory lymphomas and multiple myeloma. Dose escalation is now closed in the QD, BIW and TIW schedules but ongoing in the 5/2 schedule to explore the potential of more frequent dosing regimens for CUDC-907's upcoming investigation in patients with hematologic and solid tumors.

The 120 mg TIW dose of CUDC-907 was selected for investigation in the expansion phase after a comprehensive analysis of safety, tolerability, pharmacokinetic (PK) and pharmacodynamic (PD) parameters of all schedules tested in the ongoing Phase 1 trial. This dose and schedule was shown to be tolerable with minimal dose interruptions or reductions. To date, diarrhea and hyperglycemia have been the only dose limiting toxicities reported in the ongoing trial across all doses and schedules tested. Predictable side effects observed include gastrointestinal, hematologic and endocrine (for example, hyperglycemia) adverse events, all of which are consistent with CUDC-907's mechanism of action of inhibiting HDAC and PI3K activities. In addition, PD analyses of tissue samples from patients dosed at 120 mg TIW in the dose escalation phase demonstrate modulation of HDAC and PI3K activities in surrogate tissues such as skin and peripheral blood mononuclear cells, respectively.

About the Upcoming Solid Tumor Phase 1 Study

The solid tumor trial will be an open label, multi-center study to assess CUDC-907 in subjects with advanced, relapsed solid tumors, including hormone receptor positive breast cancer. The primary objective of this study will be to determine the safety and tolerability of orally-administered CUDC-907 using TIW and 5/2 administration schedules. The secondary objectives will be to assess the PK, establish the maximum tolerated dose/biologically effective dose, recommended Phase 2 dose, evaluate biomarkers of activity and preliminary anti-cancer activity of CUDC-907.

About CUDC-907:

CUDC-907 is an oral, dual inhibitor of Class I and II HDAC, as well as Class I PI3K enzymes. Specifically, CUDC-907 is designed to inhibit HDACs 1, 2, 3, 6 and 10 and PI3K-alpha, delta and beta isoforms, the combined inhibition of which Curis believes has synergistic effects against cancer cells and their microenvironment. It is currently undergoing investigation in a first-in-human trial to assess its safety, pharmacokinetics and preliminary anti-cancer activity in patients with relapsed/refractory lymphomas and multiple myeloma. The development of CUDC-907 is in part funded by The Leukemia & Lymphoma Society (LLS) under an agreement established in 2011 between Curis and LLS's Therapy Acceleration Program. For additional details of CUDC-907's Phase I study, please refer to www.clinicaltrials.gov (study identifier: NCT01742988).

About Curis, Inc.

Curis is an oncology-focused biotechnology company developing novel drug candidates for the treatment of human cancers. Curis' pipeline of drug candidates includes CUDC-907, a dual HDAC and 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 partner Debiopharm is studying HSP90 inhibitor, Debio 0932 in patients with advanced lung cancer. 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 Curis' expectations regarding: its plans and timing for conducting ongoing and planned clinical studies with CUDC-907 in various indications; the potential benefits of CUDC-907; and its expectations regarding further funding of the CUDC-907 development program by LLS. 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 June 30, 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 of the forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by law.

CONTACT: For More
Information:

Mani Mohindru, Ph.D.

Vice President, Corporate Strategy and Investor Relations

Curis, Inc.

617-503-6605

mmohindru@curis.com

Michael P. Gray

Chief Financial and Chief Business Officer

Curis, Inc.

617-503-6632

mgray@curis.com
