# Curis Reports CUDC-907 Preliminary Data From the Ongoing Phase 1 Trial at ASH 2013 Annual Meeting

## CUDC-907 (HDAC and PI3K inhibitor) demonstrates preliminary evidence of clinical activity
## Dose escalation ongoing with intermittent oral administration schedule in patients with relapsed/refractory lymphoma or multiple myeloma

LEXINGTON, Mass., Dec. 9, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused company developing novel, targeted drug candidates for the treatment of human cancers, today announced preliminary first-in-human results from its ongoing Phase 1 trial of CUDC-907. These data will be presented today at the 55th Annual Meeting of the American Society of Hematology (ASH) in New Orleans, LA. Intermittent oral dosing of CUDC-907 appears to be better tolerated than continuous daily dosing (QD), which demonstrated preliminary evidence of anti-tumor activity with a partial response (PR) observed in 1 patient. In addition, stable disease (SD) has been observed in 7 of 11 response-evaluable patients. CUDC-907 is an oral, dual inhibitor of histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K) enzymes that is currently under investigation in a Phase 1 trial in patients with relapsed/refractory lymphoma or multiple myeloma (MM).

"We are encouraged by the preliminary results of our ongoing Phase 1 study and will further explore clinical activity signals when administering CUDC-907 on intermittent dosing schedules," said Dr. Ali Fattaey, Ph.D., Curis' President and Chief Operating Officer. "After establishing a safe and tolerable dose range for the intermittent schedules, we expect to initiate the expansion phase of this study followed by mid-stage clinical trials in one or more hematologic malignancies in the second half of 2014."

"CUDC-907's unique mechanism of action and its promising early clinical profile support further investigation in patients with aggressive lymphomas or multiple myeloma," said Dr. Jaye Viner, M.D., M.P.H, Curis' Executive Vice President and Chief Medical Officer.

The dose escalation study was designed to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose, as well as preliminary anti-cancer activity of single agent CUDC-907 in patients with relapsed/refractory lymphoma or MM. At the time of data cut-off for the ASH presentation, 13 patients had received daily (QD) or twice weekly (BIW) regimens at doses of 30 mg QD (n=7), 60 mg QD (n=3) or 60 mg BIW (n=3). More recently, investigators began enrolling patients in a third dosing schedule in which CUDC-907 is administered thrice weekly (TIW).

Dose limiting toxicities (DLTs) of Grade 3 diarrhea and Grade 4 hyperglycemia were reported in 1 patient at the 60 mg QD dose. Treatment-related serious adverse events (AEs) of Grade 3 epistaxis (30 mg QD, n=1), and Grade 3 diarrhea and Grade 4 hyperglycemia (60 mg QD, n=1) were also reported with the daily schedule. To date, the most frequent (reported in ≥ 2 patients) Grade 3 or 4 AEs include thrombocytopenia, diarrhea and neutropenia, thus far only with the QD administration schedule. Toxicities have limited the ability to further dose escalate using the QD schedule. By contrast, no DLTs or dose interruptions have been reported for patients enrolled onto the BIW regimen at the 60mg dose level.

Eleven of the 13 patients included in the ASH presentation were evaluable for response assessment per protocol. One of these patients had mixed follicular lymphoma/ diffuse large B cell lymphoma and achieved a PR (70% reduction in a single target lesion) at the 30 mg QD dose level. Seven other patients have met criteria for SD, including 4 with SD lasting at least 4 cycles of treatment. One of these patients (MM) is currently in Cycle 13.

Preliminary pharmacokinetic analysis shows low CUDC-907 plasma levels as compared to its M1 and M2 (PI3K-active) metabolite species. This is consistent with animal studies that demonstrated higher levels of CUDC-907 in tissues as compared to plasma. Additional pharmacokinetic and pharmacodynamic analyses are ongoing.

**About CUDC-907**

CUDC-907 is a 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. In preclinical studies, CUDC-907 has demonstrated the ability to suppress multiple nodes of cellular survival and proliferation signaling pathways. In addition, preclinical data have shown that CUDC-907 inhibits compensatory pathways that are often utilized in cancer cells during the emergence of resistance to standard-of-care agents.

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.

**About the LLS Agreement**

Under the agreement between Curis and LLS, LLS is expected to fund approximately 50% of the direct costs associated with the development of CUDC-907 through milestone payments that are contingent upon the achievement by Curis of specified clinical objectives, up to a maximum of $4 million. To date, Curis has earned $1.65 million in milestone payments from LLS. In January 2013, Curis initiated a Phase 1 dose escalation clinical trial of CUDC-907 in patients with relapsed/refractory lymphomas or multiple myeloma. If the parties agree the Phase 1 study is successful, the agreement also provides for LLS to support CUDC-907's subsequent Phase 1b or Phase 2a study in one or more specific indications as well as Curis' ongoing investigation of biomarkers for CUDC-907 in these diseases, subject to the $4 million maximum funding amount. Under certain conditions associated with the successful partnering or commercialization of CUDC-907, Curis may be obligated to make payments to LLS.

**About Curis, Inc.**

Curis is an oncology-focused drug development company seeking to develop and commercialize next generation targeted small molecule 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 leveraging its experience in targeting signaling pathways to develop proprietary targeted cancer programs, including

CUDC-427, a small molecule antagonist of IAP proteins, and CUDC-907, a dual HDAC and PI3K 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 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 September 30, 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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