Curis Reports CUDC-907 Data From the Ongoing Phase 1 Trial at the 2015 ASCO Annual Meeting

CUDC-907 (HDAC and PI3K Inhibitor) Demonstrates Objective Responses, Including Complete Responses, in Patients With Relapsed/ Refractory DLBCL

Expansion Phase Ongoing in Patients With Relapsed/ Refractory DLBCL With Recommended Dose and Schedule as Monotherapy and in Combination With Standard Dose of Rituximab

LEXINGTON, Mass., May 31, 2015 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), a biotechnology company focused on the development and commercialization of innovative drug candidates for the treatment of human cancers, today announced results from the completed dose escalation and ongoing expansion stages of a Phase 1 trial of CUDC-907, an oral dual inhibitor of histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K) enzymes. Data were presented at the Annual Meeting of American Society of Clinical Oncology (ASCO) that is being held in Chicago, IL. At the recommended Phase 2 dose and schedule, CUDC-907 has demonstrated evidence of clinical activity with objective responses observed in patients with relapsed/ refractory diffuse large B cell lymphoma (DLBCL) and Hodgkin's lymphoma (HL). Two complete responses (CRs) and 4 partial responses (PRs) were reported in 10 response evaluable patients with DLBCL, including 3 responses (1 CR and 2 PRs) in patients with transformed follicular lymphoma (t-FL/DLBCL), a very difficult to treat subset of DLBCL. One patient with HL experienced partial response out of a total of 12 response evaluable patients with HL. In addition, stable disease (SD) has been observed in 25 of 44 response evaluable patients across various lymphomas and multiple myeloma (MM).

"Despite a number of investigational agents being tested in patients with DLBCL, this disease continues to be an area of significant unmet need, especially in the relapsed/ refractory setting," said Dr. Anas Younes, MD, Chief of the Lymphoma Service of the Memorial Sloan Kettering Cancer Center in New York City and the Principal Investigator of the study. "The single agent activity of CUDC-907, especially in patients with relapsed/ refractory DLBCL is promising and supports its further investigation in this disease."

"We are pleased to have determined a safe and tolerable dose and schedule for the administration of CUDC-907 and are encouraged to see objective responses in patients with advanced, relapsed/ refractory DLBCL," said Ali Fattaey, Ph.D., Curis' President and Chief Executive Officer. "After completing the expansion arms of the ongoing trial in patients with relapsed/ refractory DLBCL treated with CUDC-907 either as monotherapy or in combination with rituximab, we expect to initiate a registration directed Phase 2 study in this patient population later this year."

The Phase 1 dose escalation and expansion study was designed to determine the maximum tolerated dose (MTD) and recommended Phase 2 dose, as well as preliminary anti-cancer activity of oral CUDC-907 in patients with relapsed/ refractory lymphoma or MM. As of the April 27, 2015 data cut-off for the ASCO presentation, a total of 57 patients had been enrolled in the study, with 40 and 17 patients in the dose escalation and expansion phases of the study, respectively. In the completed dose escalation phase, patients either received CUDC-907 daily (QD, doses: 30 or 60 mg), or intermittently on twice weekly (BIW) or thrice weekly (TIW) schedules (daily doses: 60, 90, 120 or 150 mg), or on a 5 days on, 2 days off (5/2) schedule (dose: 60 mg). In the ongoing expansion phase, patients either receive CUDC-907 60 mg on the 5/2 schedule or 120 mg on the TIW schedule.

Low grade (Grade 1 and 2) diarrhea, fatigue and nausea were the most common drug related adverse events (AEs) reported in the study. Diarrhea and hyperglycemia are the only dose limiting toxicities (DLTs) reported. A total of 4 of these DLTs occurred in 3 patients treated at the highest doses on the QD (60 mg) and intermittent schedules (150 mg BIW and TIW). Other drug related Grade 3 or 4 AEs reported in 2 or more patients included thrombocytopenia and neutrophil decrease (hematologic AEs) as well as diarrhea, hyperglycemia and fatigue (non-hematologic AEs). The recommended Phase 2 dose of 60 mg 5/2 was reasonably well tolerated and is currently undergoing further examination in the expansion phase of the trial in patients with relapsed/ refractory DLBCL.

Forty-four of the 57 patients included in the ASCO presentation were evaluable for response assessment per protocol. Of the 16 patients with DLBCL enrolled across the dose escalation and expansion phases of the study, 10 were evaluable for disease response at the time of data cut-off. The best responses observed in these patients were CR (2 patients), PR (4 patients) SD (2 patients) and progressive disease, or PD (2 patients), with median duration on treatment of 3 months (range: 1.4-24.2 months, ongoing). The overall median duration on treatment for these 16 patients was 50 days. Objective responses were observed in patients with different subtypes of DLBCL, including germinal center B cell lymphoma (GCB) as well as in 3 patients with t-FL/ DLBCL.

Indication	N	Best Response, N (%)					Median Treatment
		CR	PR	SD	PD	NE**	Duration, days (range)
All DLBCL*	16	2 (13)	4 (25)	2 (13)	2 (13)	6 (38)	50 (5-727+)
> t-FL/DLBCL	7	1 (14)	2 (29)	2 (29)	--	2 (29)	96 (5-287+)
HL	14	--	1 (7)	8 (57)	3 (21)	2 (14)	106 (7-271+)
MM	9	--	--	4 (44)	2 (22)	3 (33)	71 (43-825+)
Other lymphoma	18	--	--	11 (61)	5 (28)	2 (11)	60 (17-468+)
Total	57	2 (4)	5 (9)	25 (44)	12 (21)	13 (23)	71 (5-825+)

* Includes t-FL/DLBCL and DLBCL

**44 patients were evaluable for disease response as of the April 27, 2015 data cut-off. NE includes patients who received less than 1 cycle of treatment (N=12) and one patient who has yet to be re-staged. Withdrawal from treatment during Cycle 1 was due to toxicity / AE (N=5), physician decision (N=3), PD (N=3) or withdrawal of consent (N=1).

Consistent with preclinical observations, pharmacokinetic analysis shows significant levels of CUDC-907 in tumor tissue obtained from one patient. Pharmacodynamic analyses of the peripheral blood mononuclear cells isolated from patients show consistent modulation of HDAC and PI3K pathways, as demonstrated by increased levels of acetylated of histone H3 and decreased levels of phosphorylated AKT proteins. Further pharmacokinetic and pharmacodynamic analyses are ongoing.

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. CUDC-907 is currently undergoing investigation in a Phase 1 trial to assess its safety, pharmacokinetics and preliminary anti-cancer activity in patients with relapsed/ refractory lymphomas and multiple myeloma. The U.S. Food and Drug Administration (FDA) recently granted orphan drug designation to CUDC-907 for the treatment of DLBCL. CUDC-907 is also being investigated in a separate Phase 1 trial in patients with advanced solid tumors including those with hormone receptor positive breast cancer or with NUT midline carcinoma. The development of CUDC-907 is in part supported by The Leukemia & Lymphoma Society (LLS) under a funding agreement established in 2011 between Curis and LLS's Therapy Acceleration Program. For additional details of CUDC-907's Phase 1 studies, please refer to www.clinicaltrials.gov (study identifiers: NCT01742988 and NCT02307240).

About Curis, Inc.

Curis is a biotechnology company focused on the development and commercialization of innovative drug candidates for the treatment of human cancers. Curis' pipeline of drug candidates includes CUDC-907, a dual HDAC and PI3K inhibitor, CUDC-427, a small molecule antagonist of IAP proteins, and CUDC-305, an oral HSP90 inhibitor. Curis is also engaged in a broad collaboration with Aurigene in the areas of immuno-oncology and precision oncology. As part of this collaboration, Curis expects to exercise options to exclusively license oral small molecule antagonists of PD-L1 and IRAK4. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are developing and commercializing Erivedge® for the treatment of advanced basal cell carcinoma.

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 and the potential benefits of CUDC-907, among others. 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. There can be no guarantee that Curis' collaboration agreement with Aurigene will continue for its full term, that Curis or Aurigene will maintain the financial resources necessary to continue financing its portion of research, development and commercialization costs or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Genentech and Roche may experience delays or failures in the manufacture and commercialization of Erivedge, regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to develop or commercialize Erivedge, and competing drugs may be developed that are superior to Erivedge, any of which could adversely affect the amount of royalty revenue that Curis receives from sales of Erivedge. Curis also faces risks relating to its wholly-owned subsidiary's Erivedge royalty-collateralized loan transaction, including the risk that it may not receive sufficient levels of royalty revenue from sales of Erivedge to satisfy the debt obligation or may otherwise lose its rights to royalties and royalty-related payments as a result of a foreclosure of the loan. 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 will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. 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 Annual Report on Form 10-Q for the quarter ended March 31, 2015 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.

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