Curis Reports Third Quarter 2013 Financial Results and Provides CUDC-427 Development Update

CUDC-427 Phase 1 Trial Placed on Partial Clinical Hold by FDA
Company to Host Conference Call Today at 8:30 a.m. EST

LEXINGTON, Mass., Nov. 6, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused company seeking to develop novel, targeted drug candidates for the treatment of human cancers, today provided an update on the Phase 1 clinical trial of its oral inhibitor of apoptosis (IAP) antagonist, CUDC-427 and reported its financial results for the third quarter ended September 30, 2013.

CUDC-427 Phase 1 Study Clinical Trial Update

On November 5, 2013, the Company received written notification from the United States Food and Drug Administration (FDA) that its Phase 1 study of CUDC-427 has been placed on partial clinical hold following the report of death of a patient who progressed to liver failure approximately one month following the discontinuation of CUDC-427 dosing. Under this partial clinical hold, new patients may not be enrolled in the study until Curis provides the FDA with requested additional data and analysis on patients treated with CUDC-427 and a proposed protocol amendment is submitted to and accepted by the FDA. The Company expects to respond to the FDA's requests for additional information and also plans to submit an amendment to the current protocol in a timely manner.

The current open-label, single-agent, dose escalation Phase 1 study of CUDC-427 was initiated in the third quarter of 2013 in patients with advanced and refractory solid tumors or lymphomas. The study was designed to determine the maximum tolerated dose (MTD) and recommended single-agent Phase 2 dose of CUDC-427 using a continuous, twice-daily treatment schedule. One patient with breast cancer metastatic to the liver, lungs, bone and ovaries developed serious adverse events related to liver function, including increases in serum levels of AST and ALT enzymes and bilirubin. Unlike prior clinical experience with CUDC-427, this patient's liver enzyme levels did not recover in response to CUDC-427 discontinuation, and the patient died of liver failure approximately one month following the discontinuation of CUDC-427 dosing. While elevations in liver enzyme levels have previously occurred in patients receiving CUDC-427, no other patients in this or a prior Phase 1 CUDC-427 trial have experienced a serious adverse event of this nature. There are no patients currently being treated with CUDC-427 in this study as all other patients enrolled in this study have discontinued dosing due to disease progression or patient or physician discretion during the ordinary course of the study.

"We are profoundly grateful to and inspired by this patient and all other patients who volunteer to participate in clinical trials. Our thoughts are with this patient's family and loved ones," said Ali Fattaey, President and Chief Operating Officer of Curis.

Dr. Fattaey continued, "Based on available data from treated patients, we believe that CUDC-427 could play an important role in oncology treatment, either as monotherapy or in combination with other anticancer agents. Accordingly, we will work diligently to address the FDA's request in an effort to resolve the partial clinical hold."

Curis licensed CUDC-427 from Genentech, which completed a 42-patient Phase 1 trial in 2012. No maximum tolerated dose (MTD) was determined in that study, in which CUDC-427 was administered on a once daily dosing regimen for two weeks followed by one week off treatment. Treatment-related adverse events (AEs) that were Grade 3 or higher in severity were elevated levels of AST and ALT liver enzymes (two patients at 450 and 600 mg doses, respectively) and anemia, fatigue, neutropenia, pruritus, pyrexia and rash (one patient each). AEs that resulted in treatment discontinuation were Grade 3 fatigue in one patient (the only dose limiting toxicity documented on the trial), Grade 2 QTc prolongation, Grade 2 drug hypersensitivity, Grade 2 pneumonitis (one patient each), and Grade 3 pruritus/Grade 2 rash (both AE's in one patient). Unconfirmed complete responses were observed in one patient with ovarian cancer and another patient with MALT lymphoma. A mixed response was observed in one patient with a carcinoma of unknown primary origin. Stable disease lasting longer than three months was observed in four other patients, including one with small cell lung cancer, who remained on study drug for more than 10 months.

A clinical hold is an order issued by FDA to the sponsor of an IND to delay or to suspend a clinical investigation. A clinical hold, including a partial clinical hold, involves the Agency (1) requiring additional information and/or data, (2) reviewing the additional information and/or data, and (3) after the review, informing the sponsor that they can proceed. A partial clinical hold is defined as a delay or suspension of only part of the clinical work requested under the IND (e.g., a specific protocol or part of a protocol is not allowed to proceed; however, other protocols or parts of the protocol are allowed to proceed under the IND).

Third Quarter 2013 Financial Results

Curis reported a net loss of $1.9 million, or ($0.02) per share on both a basic and fully diluted basis for the third quarter of 2013, as compared to a net loss of $3.4 million or ($0.04) per share on both a basic and fully diluted basis for the same period in 2012. Curis reported a net loss of $8.1 million, or ($0.10) per share on both a basic and fully diluted basis for the nine months ended September 30, 2013, as compared to a net loss of $4.0 million or ($0.05) per share on both a basic and fully diluted basis for the same period in 2012.

Revenues for the third quarter of 2013 were $7.2 million, as compared to $578,000 for the same period in 2012. This increase in revenues was primarily due to an increase in license revenue as the result of a $6.0 million milestone earned from Genentech/Roche upon the conditional approval of Erivedge® (vismodegib) by the European Commission in July 2013. In addition, royalties received from Genentech/Roche's net sales of Erivedge during the quarter also increased to $1.1 million, as compared to $446,000 during the same period in 2012.

Revenues for the nine months ended September 30, 2013 were $13.5 million, as compared to $15.3 million for the same period in 2012. The decrease in revenues for the nine-month period was primarily due to a decrease in our license fee revenues from Genentech, which included a $10 million milestone payment upon FDA approval of Erivedge® in January 2012 as compared to the $6 million earned in the third quarter of 2013. This decrease was partially offset by an increase in royalty revenues, which were $2.5 million and $970,000 for the nine month periods ending September 30, 2013 and 2012, respectively. During the nine months ended September 30, 2013, Curis also recorded $650,000 in milestone payments received from The Leukemia and Lymphoma Society (LLS).

Operating expenses for the third quarter of 2013 were $7.1 million, as compared to $5.5 million for the same period in 2012. Operating expenses for the nine months ended September 30, 2013 were $18.4 million, as compared to $20.5 million for the same period in 2012.

Costs of royalty revenues, which were comprised of amounts due to third-party university patent licensors in connection with Genentech/Roche's Erivedge net sales, were $54,000 and $22,000 during the third quarters of 2013 and 2012, respectively. Costs of royalty revenues for the nine months ended September 30, 2013 were $127,000, as compared to $148,000 for the same period in 2012.

Research and development expenses were $4.2 million for the quarter, as compared to $3.0 million for the same period in 2012. This increase was primarily due to $1.9 million in expenses incurred in the development of CUDC-427. Curis also incurred $300,000 in research and development expenses during the quarter related to the conditional approval of Erivedge in the European Union in July 2013. Offsetting these increases, Curis decreased its spending on CUDC-101 and discovery research to $420,000 during the third quarter of 2013 from $1.9 million during the same period in 2012, as the Company shifted its capital resources to the development of CUDC-907 and CUDC-427. Research and development expenses were $10.0 million for the nine months ended September 30, 2013 as compared to $12.8 million for the same period in 2012.

General and administrative expenses were $2.8 million for the third quarter of 2013, as compared to $2.5 million for the same period in 2012. The increase was primarily due to increased expenses for personnel, legal services and professional services. General and administrative expenses were $8.3 million for the nine months ended September 30, 2013 as compared to $7.5 million for the same period in 2012.

Other expense was $2.0 for the third quarter of 2013, as compared to other income of $1.6 million for the same period in 2012. The increase in other expense was primarily the result of $1.0 million in interest expense and amortization of debt issuance costs related to the loan made by BioPharma II to Curis Royalty, a wholly-owned subsidiary of Curis. In addition, Curis recognized $1.1 million in other expense during the quarter as a result of an increase in the fair value of a warrant liability. Other income during the third quarter of 2012 primarily represented the change in the fair value of this warrant liability. Other expense was $3.2 million for the nine months ended September 30, 2013 as compared to other income of $1.1 million for the same period in 2012.

As of September 30, 2013, Curis' cash, cash equivalents, marketable securities and investments totaled $67.1 million and there were approximately 84.1 million shares of common stock outstanding.

In December 2012, Curis' wholly-owned subsidiary Curis Royalty received a $30,000,000 loan at an annual interest rate of 12.25% pursuant to a credit agreement between Curis Royalty and BioPharma-II. In connection with the loan, Curis transferred to Curis Royalty its right to receive certain future royalty and royalty-related payments on the commercial sales of Erivedge that it may receive from Genentech. The loan and accrued interest will be repaid by Curis Royalty using such royalty and royalty-related payments. To secure repayment of the loan, Curis Royalty granted a first priority lien and security interest (subject only to permitted liens) to BioPharma-II in all of its assets and all real, intangible and personal property, including all of its right, title and interest in and to the royalty and royalty-related payments. The loan constitutes an obligation of Curis Royalty, and is intended to be non-recourse to Curis. For 2013, Curis Royalty is required to pay BioPharma II up to $1.0 million per quarter of the royalty revenues that it receives from Genentech/Roche. Curis expects that all or a significant portion of the Erivedge royalties received by Curis Royalty will be paid to BioPharma II until the debt is repaid.

As of June 30, 2013, Curis had recorded liabilities related to the loan of $30,709,000, which consisted of $30,397,000 in long- and short-term debt, net and accrued interest of $312,000. During the quarter Curis recorded interest and amortization of certain debt issuance costs totaling $965,000 and Curis Royalty made a payment on August 30, 2013 to BioPharma II of $765,000, resulting in debt-related liabilities of $30,896,000 as of September 30, 2013, which consisted of $30,582,000 in long- and short-term debt, net and accrued interest of $314,000.

During the third quarter of 2013, the Company received $9.6 million in net proceeds relating to the sale to the public of 2.29 million shares of its common stock pursuant to its July 2013 at-the-market sales agreement with Cowen and Company, LLC. In addition, the Company received an additional $6.8 million in net proceeds through the sale of an additional 1.56 million shares, which settled in early October.

"Our financial position continues to be strong, with expected cash, cash equivalents and investments at year-end of between $67 and $70 million, which we believe will provide us with adequate capital to fund our planned operations into 2016," commented Michael Gray, Chief Business and Chief Financial Officer of Curis. "We were pleased that Erivedge royalty revenues increased by over 30% sequentially, and look forward to investing further in our developing pipeline."

Recent Operational Highlights

Erivedge:

- Genentech/Roche initiated a Phase 1b/2 study of Erivedge to investigate the safety and efficacy of the drug in patients with relapsed/ refractory AML and relapsed or refractory high-risk MDS.

The European Commission granted conditional approval to Erivedge for the treatment of adult patients with symptomatic metastatic basal cell carcinoma (BCC) or locally advanced BCC inappropriate for surgery or radiotherapy. This regulatory decision is applicable to all 28 member states of the European Union. Erivedge is being commercialized and developed by Genentech/Roche under a collaboration agreement between Curis and Genentech/Roche. Curis earned a $6 million milestone payment from Genentech/Roche upon the conditional approval of Erivedge.

Debio 0932

Debiopharm initiated an open-label, multicenter Phase 1 dose-finding study of Debio 0932 in combination with everolimus, in patients who have been previously treated with a VEGF-directed tyrosine kinase inhibitor.

Corporate:

Curis appointed Jaye Viner, M.D., M.P.H as Chief Medical Officer and Executive Vice President. Dr. Viner will be responsible for the leadership of Curis' clinical development strategy and efforts to further the development of its pipeline of proprietary drug candidates. Curis also appointed Tania Chander, Pharm.D. as Vice President of Product Development. Dr. Chander will be responsible for project leadership throughout the product development process.

Upcoming Activities

Curis expects to present at the following investor and medical conferences through December 2013:

2013 RBC Capital Markets' Healthcare Investor Day on November 21, 2013 in Denver
Brean Capital 2013 Life Sciences Summit on November 25, 2013 in New York City
2013 Deutsche Bank BioFEST on December 2-3, 2013 in Boston
Piper Jaffray 25th Annual Healthcare Conference on December 3-4, 2013 in New York City
55th American Society of Hematology (ASH) Annual Meeting and Exposition on December 7-10, 2013 in New Orleans
Oppenheimer 24th Annual Healthcare Conference on December 10-11, 2013 in New York City

Conference Call Information

Curis management will host a conference call today, November 6, 2013, at 8:30 a.m. ET, to discuss Curis' financial results for the third quarter as well as provide a corporate update.

To access the live conference call, please dial (877) 868-1829 from the U.S. or (253) 237-1135 from other locations, shortly before 8:30 a.m. ET. The conference ID number is 86137584. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section. A replay will be available approximately two hours after the completion of the call through 12:00 p.m. ET, Friday, November 15, 2013. To access the replay, please dial (855) 859-2056 from the United States or (404) 537-3406 from other locations and reference conference ID number 86137584.

About Curis, Inc.

Curis is an oncology-focused drug development company seeking to develop novel drug candidates for the treatment of human cancers. Erivedge is the first and only FDA-approved medicine for the treatment of advanced BCC 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 seeking to further the development of its pipeline of proprietary targeted cancer drug candidates, including CUDC-427, a small molecule antagonist of IAP proteins, and CUDC-907, a dual PI3K and HDAC inhibitor. 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 the Company's clinical development plans and timelines, any expressed or implied statements about the efficacy and safety of its drug candidates, including CUDC-427 and CUDC-907, any statements about its efforts to satisfactorily respond to the FDA's request for data and analysis in response to the partial clinical hold on CUDC-427 or about future development of CUDC-427 in view of the partial clinical hold, its expectations regarding growth in Erivedge sales and successful commercialization in additional markets, and the expected benefit of patent issuances, its plans to present data at ASH and its estimates with respect to its cash and cash equivalent balances at year end. Forward-looking statements 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 satisfactorily respond to the FDA's request for additional data and analysis regarding CUDC-427. The FDA may not lift the clinical hold and allow Curis to pursue further development of CUDC-427, and even if the FDA lifts the clinical hold, or if the FDA or other regulatory agencies continue to express safety concerns even after the hold is lifted, future preclinical or clinical studies involving CUDC-427 may be more burdensome or include additional preclinical or clinical endpoints that are difficult to meet. Genentech and Roche may not obtain additional regulatory approvals for Erivedge abroad. Genentech and Roche may experience delays or failures in the manufacture of Erivedge. Erivedge's benefit/risk profile may not be widely accepted by the medical community or third-party payors for the treatment of advanced BCC, in which case revenues from sales of Erivedge could be adversely affected. Regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to develop or commercialize Erivedge. Competing drugs may be developed that are superior to Erivedge. Curis 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 and its collaborators may experience adverse results, delays and/or failures in their drug development programs. Curis and its collaborators' drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical trials and/or may never achieve the requisite regulatory approval needed for commercialization. Curis will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. Curis may not obtain or maintain necessary patent protection and could become involved in expensive and time consuming patent litigation and interference proceedings. Curis faces substantial competition. 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 period ended June 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.

CURIS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(UNAUDITED)

	Three months ended September 30,		*Nine months ended September 30,*	
	2013	*2012*	*2013*	*2012*
Revenues:				
Royalties	$ 1,080,233	$ 446,402	$ 2,549,945	$ 969,774
License Fees	6,000,000	—	10,000,000	14,000,000
Research and development	121,850	131,357	927,950	315,811
Total revenues:	7,202,083	577,759	13,477,895	15,285,585
Operating expenses:				
Costs of revenues	54,014	22,320	127,499	148,489
Research and development	4,170,751	3,042,498	9,965,847	12,784,902
General and administrative	2,846,950	2,473,853	8,317,741	7,539,516
Total operating expenses	7,071,715	5,538,671	18,411,087	20,472,907
Net income (loss) from operations	130,368	(4,960,912)	(4,933,192)	(5,187,322)
Interest income	39,024	34,129	117,585	87,224
Interest expense	(964,543)	—	(2,870,087)	—
Change in fair value of warrant liability	(1,072,687)	1,541,779	(438,286)	1,054,379
Other income (expense), net	(1,998,206)	1,575,908	(3,190,788)	1,141,603
Net loss	$ (1,867,838)	$ (3,385,004)	$ (8,123,980)	$ (4,045,719)
Basic and diluted net loss per common share	$ (0.02)	$ (0.04)	$ (0.10)	$ (0.05)
Basic and diluted weighted average common shares outstanding	82,456,708	79,639,433	81,235,922	78,752,687

CURIS, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(UNAUDITED)

	September 30, 2013	*December 31, 2012*
ASSETS		
Cash, cash equivalents and investments	$ 67,138,656	$ 58,701,423
Investments — restricted	180,364	194,282

Accounts receivable	1,156,469	908,064
Property and equipment, net	467,489	434,168
Goodwill	8,982,000	8,982,000
Other assets	621,998	548,412
Total assets	$ 78,546,976	$ 69,768,349
LIABILITIES AND STOCKHOLDERS' EQUITY		
Accounts payable, accrued expenses and other liabilities	4,465,518	4,173,747
Debt, net	30,581,655	29,838,925
Warrant liability	1,926,465	1,488,179
Total liabilities	36,973,638	35,500,851
Total stockholders' equity	41,573,338	34,267,498
Total liabilities and stockholders' equity	$ 78,546,976	$ 69,768,349

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 Business and Chief Financial Officer

Curis, Inc.

617-503-6632

mgray@curis.com
