Curis Presents Early Clinical Pharmacokinetic and Biomarker Data from CA-170's Phase 1 Trial at the SITC 2016 Conference

LEXINGTON, Mass., Nov. 09, 2016 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of cancer, today presented preliminary clinical pharmacokinetic (PK) and early biomarker data from the ongoing dose escalation stage of CA-170's Phase 1 trial at the Society for Immunotherapy of Cancer (SITC) 31st Annual Meeting & Associated Programs in National Harbor, MD. CA-170 is a potent and selective, orally available small molecule antagonist of the programmed death ligand-1 (PDL1) and V-domain Ig suppressor of T cell activation (VISTA) immune checkpoints.

CA-170 is the first orally available small molecule immune checkpoint antagonist to be investigated in cancer patients. Preclinical data presented previously demonstrated dose-dependent oral exposure in multiple non-clinical models, as well as immune modulation and anti-tumor activity with CA-170 in multiple syngeneic mouse tumor models. Clinical data from a limited number of patients in the Phase 1 trial presented at the SITC conference, demonstrate that similar to the preclinical findings, CA-170 has a dose proportional and predictable PK profile in patients treated orally at various doses in the ongoing dose escalation stage of the study. Further, evaluation of patient blood samples demonstrate that CA-170 appears to be biologically active in modulating the immune system, with a several-fold increase in percentage of circulating CD8+ T cells expressing activation markers within 24 hours of oral dosing.

The clinical findings were presented in an oral session at SITC by David Tuck, MD, Chief Medical Officer of Curis. Additional details will be presented during the conference at a poster session on Friday, November 11 at 12:15pm. In addition to the CA-170 data, Curis's collaborator, Aurigene will also present pre-clinical data from the PDL1/ T-cell immunoglobulin and mucin domain containing protein-3 (TIM-3) program at a poster session on Saturday, November 12 at 11:45am.

"We are pleased with these early PK and biomarker data demonstrating that CA-170 performs in a predictable manner in patients, and very similar to what we observed in the preclinical setting. It is encouraging to observe significant drug exposure at the starting clinical dose, as well as increasing drug exposure with ascending doses. Based on the increase in the proportion of activated CD8^{+} T cells in blood samples of treated patients, we believe that CA-170 is biologically active in immune modulation by functioning as a checkpoint antagonist at these exposure levels using once daily oral dosing," said Ali Fattaey, Ph.D., Curis's President and CEO. "These initial patient data also affirm our belief in this innovative small molecule checkpoint targeting strategy invented by our partner Aurigene, and we plan to continue to advance and expand this technology. We look forward to CA-170's continued clinical development, as well as bringing our second small molecule, oral checkpoint inhibitor in this collaboration, CA-327, which targets PDL1 and TIM3 into clinical studies next year."

Figure 1: Preliminary Patient PK data from CA-170 Phase 1 trial

	Patient Plasma Cycle 1 Day 1			
Dose (mg)	**50**	**100**	**200**	**400**
T1/2 (hours)	8.7	9.6	5.3	12.9
Cmax (ng/mL)	412	1107	1998	4100
AUClast (hr*ng/mL)	5197	11019	27488	66664

T1/2: half life; Cmax: maximum concentration; AUC: Area under the curve

Figure 2: Preliminary Biomarker Data (Activated CD8+ T cells)

A graphic accompanying this release is available at http://www.globenewswire.com/NewsRoom/AttachmentNg/41a88bab-ffb3-47be-bf0d-2191edbda4c3

About CA-170
CA-170 is a first-in-class, orally available, small molecule that was rationally designed to target and inhibit the immune checkpoints, Programmed Death Ligand-1 (PDL1) and V-domain Immunoglobulin Suppressor of T-cell Activation (VISTA). CA-170 is currently being evaluated in a Phase 1 study to assess safety, tolerability and pharmacokinetics of ascending doses of CA-170 in patients with advanced solid tumors or lymphoma (clinicaltrials.gov identifier: NCT02812875).

About CA-327
CA-327 is an orally available, small molecule that was rationally designed to target and inhibit the immune checkpoints, Programmed Death Ligand-1 (PDL1) and T-cell immunoglobulin and mucin domain containing protein-3 (TIM3). CA-327 is currently undergoing IND-enabling studies.

About Curis, Inc.
Curis is a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of human cancers, including its lead development candidate, CUDC-907 that is being investigated in clinical studies in patients with lymphomas and solid tumors. 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 has exclusive licenses to oral small molecule antagonists of the PD-1 and VISTA pathways, including PD-L1/VISTA antagonist CA-170, and oral small molecule antagonists of the PD-1 and TIM-3 pathways, including PD-L1/TIM-3 antagonist CA-327, as well as to molecules designed to inhibit the IRAK4 kinase, including CA-4948. CA-170 is currently undergoing testing in a Phase 1 trial in patients with advanced

solid tumors and lymphomas. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are commercializing Erivedge® for the treatment of advanced basal cell carcinoma, and are further developing Erivedge in other diseases including idiopathic pulmonary fibrosis and myelofibrosis. 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 potential advantages and benefits of small molecule checkpoint inhibitors and the Company's plans and expectations for the collaboration with Aurigene, including its plans to discover and develop multiple first-in-class oral, small molecule checkpoint inhibitors for the treatment of patients with cancer. 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 experience adverse results, delays and/or failures in its drug development programs and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. Curis's drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical studies and/or may never achieve the requisite regulatory approvals needed for commercialization. Favorable results seen in preclinical studies and early clinical trials of Curis's drug candidates may not be replicated in later trials. There can be no guarantee that the collaboration agreement with Aurigene will continue for its full term, that Curis or Aurigene will each maintain the financial and other resources necessary to continue financing its portion of the research, development and commercialization costs, or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to develop or commercialize Erivedge in BCC. Erivedge may not demonstrate sufficient or any activity to merit its further development in disease indications other than BCC. Competing drugs may be developed that are superior to Erivedge. Curis faces risks relating to its wholly-owned subsidiary's 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 will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. Curis faces substantial competition. Curis also faces risks relating to potential adverse decisions made by the FDA and other regulatory authorities, investigational review boards, and publication review bodies. Curis may not obtain or maintain necessary patent protection and could become involved in expensive and time-consuming patent litigation and interference proceedings. Unstable market and economic conditions and unplanned expenses may adversely affect Curis's financial conditions and its ability to access the substantial additional capital needed to fund the growth of its business. Important factors that may cause or contribute to such differences include the factors set forth under the caption "Risk Factors" in our most recent Form 10-K and Form 10-Q and the factors that are discussed in other filings that we periodically make with the Securities and Exchange Commission ("SEC").

In addition, any forward-looking statements represent the views of Curis only as of today and should not be relied upon as representing Curis's 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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