Curis and Aurigene Present Preclinical Data from Multiple Programs at AACR Annual Meeting

LEXINGTON, Mass., April 20, 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 human cancers, today announced that Curis and its collaborator, Aurigene, presented data from the following programs at the Annual Meeting of American Association of Cancer Research (AACR) in New Orleans, LA:

- Curis poster presentation on CUDC-907, an oral inhibitor of histone deacetylase (HDAC) and phosphoinositide 3-kinase (PI3K)
- Aurigene presentation on CA-170 (previously AUPM-170), a first-in-class oral, small molecule immune checkpoint antagonist targeting programmed death ligand-1 (PD-L1) and V-domain Ig suppressor of T cell activation (VISTA), as well as data from the PD-L1/ T-cell immunoglobulin and mucin-domain containing-3 (TIM-3) antagonist program
- Aurigene presentation on CA-4948, the lead compound from the interleukin-1 receptor associated kinase 4 (IRAK4) inhibitor program

"Our data show significant effect of CUDC-907 on MYC levels and the compound's antitumor activity in multiple preclinical models of MYC-altered malignancies, providing further support to the results of our Phase 1 trial where we observed objective responses in patients with DLBCL, and particularly those with MYC-altered disease," said Ali Fattaey, Ph.D., Curis' President and CEO. "The presentations by our collaborator, Aurigene not only highlight our progress in immuno-oncology with CA-170, which we look to advance into the clinic in the first half of the year, but also Aurigene's ability to extend the small molecule discovery capabilities to now target TIM3 in a separate program."

CUDC-907 presentation:

The Curis poster "*Novel dual HDAC & PI3K inhibitor, CUDC-907, for MYC-driven malignancies*" provided data on the activity of CUDC-907 in multiple MYC-altered disease models using both *in vitro* experiments and *in vivo* animal studies. Cell line and animal model studies using multiple MYC-altered DLBCL models showed that CUDC-907 had significant anti-tumor activity that correlated with the compound's effect on downregulating MYC levels in a time and dose dependent manner. This effect was independent of disease subtypes classified using other molecular markers. CUDC-907 also showed potent anti-tumor activity in multiple cell lines of NUT midline carcinoma (NMC), a rare genetically defined tumor, which also demonstrates MYC dysregulation. CUDC-907 downregulated MYC levels in NMC cell lines and was more potent than BET inhibitors in *in vitro* assays of growth inhibition. The anti-tumor effects of CUDC-907 in NMC were further confirmed in a xenograft mouse model and in several MYC-amplified patient-derived xenograft models of solid tumors.

CA-170 (PD-L1/VISTA antagonist) and small molecule PD-L1/TIM-3 antagonist presentation:

The Aurigene presentation "*Oral immune antagonist targeting PD-L1/VISTA or PD-L1/Tim3 for cancer therapy*" provided data outlining the novel approach of identification and characterization of oral antagonists of immune checkpoint proteins. The lead IND-ready molecule, CA-170, targets PD-L1 and VISTA and has an optimized pharmacologic and safety profile required for human testing. Data from a second, independent program within the collaboration with compounds that target PD-L1 and TIM-3 immune checkpoints were also presented. *In vitro* studies showed that AUPM-327, a representative molecule from the PD-L1/TIM-3 program, can rescue T cell functions that are inhibited by addition of PD-L1 or TIM-3 checkpoint proteins, but does not affect other checkpoint regulators such as VISTA, CTLA4, and LAG-3, demonstrating its selectivity. Additionally, daily oral administration of the PD-L1/TIM-3 antagonist resulted in anti-tumor activity in multiple syngeneic tumor models including melanoma and colon cancer.

IRAK4 inhibitor presentation:

The Aurigene presentation "*Efficacy and safety of highly selective novel IRAK4 inhibitors for treatment of ABC-DLBCL*" provided a detailed profile of the pharmacologic and biologic properties of the lead molecule, CA-4948. This compound has favorable drug metabolism as well as pharmacokinetics properties and appears to have a clean *in vitro* toxicity profile. CA-4948 showed potent anti-tumor activity *in vivo* in two models of MYD88 mutant- DLBCL disease. CA-4948 also had potent anti-inflammatory effects in a rodent model of inflammation suggesting the potential use of an IRAK4 inhibitor in both cancer and inflammatory diseases.

Curis has exclusive licenses to CA-170 and CA-4948 under a collaboration agreement with Aurigene established in 2015.

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, a dual HDAC and PI3K inhibitor 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 pathway/ VISTA, including PD-L1/VISTA antagonist CA-170, as well as to molecules designed to inhibit IRAK4, including CA-4948. 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 Company's plans, strategies and prospects and the potential benefits of its drug development programs. Forward-looking statements used in this press release may also contain the words "believes," "expects," "anticipates," "plans," "seeks," "estimates," "assumes," "will," "may," "could" or similar expressions. These forward-looking statements 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' expectations could be affected by risks and uncertainties relating to adverse results of clinical trials and preclinical studies, including subsequent analysis of existing data and new data received from ongoing and future studies, the content and timing of decisions made by the U.S. Food & Drug Administration and other regulatory authorities, investigational review boards at clinical trial sites, and publication review bodies, and Curis' ability to enroll patients in clinical trials. Moreover, 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 each 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. 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 from other companies developing cancer therapeutics. Unstable market and economic conditions and developments relating to Curis' business may adversely affect Curis' financial condition 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-K for the year ended December 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 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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