Curis and Aurigene Announce CA-170 Program Update Following Data Presented at ESMO 2017

Results from 34 Patients Demonstrate Positive Safety Profile and Support Decision to Expand Development

Aurigene and Curis Plan Clinical Trial of CA-170 in India

LEXINGTON, Mass., Sept. 11, 2017 (GLOBE NEWSWIRE) -- Curis, Inc. (NASDAQ:CRIS), a biotechnology company focused on the development and commercialization of innovative and effective therapeutics for the treatment of cancer, today presented preliminary data from the initial 34 patients with cancer treated in the dose escalation stage of the Phase 1 trial of CA-170 conducted in the U.S., South Korea and Spain, at the European Society for Medical Oncology (ESMO) 2017 Congress. As a result of the initial safety data and preliminary evidence of clinical benefit observed in the trial, Curis's collaborator and discoverer of CA-170, Aurigene Discovery Technologies Limited, a specialized biotechnology company engaged in discovery and early clinical development of novel and best-in-class therapies to treat cancer and inflammatory diseases, today announced plans to initiate a Phase 2 trial of CA-170 to be conducted at sites in India.

"We are pleased with these early results. Based on evidence of tumor shrinkage, multiple patients remaining on drug treatment for extended periods, and compelling signals for biomarkers of immune modulation in patient blood and tumor samples, we remain highly confident that the CA-170 program is moving in the right direction. We plan to continue with the dose escalation and continued analysis of patient biopsy samples in the Phase 1 trial," said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. "We expect to provide additional updates at upcoming conferences including the Society for Immunotherapy of Cancer (SITC) annual meeting in November."

"The ability for cancer patients to administer a potential checkpoint inhibitor on their own as a once daily oral drug is a significant and unique opportunity in our field," added Adil Daud, M.D., investigator in the CA-170 Phase 1 trial and director of Melanoma Clinical Research at the UCSF Helen Diller Family Comprehensive Cancer Center. "These initial clinical results are encouraging and merit continued development."

"These results are consistent with the observations made in the preclinical setting and further affirm CA-170's mechanism of action as an oral small molecule checkpoint inhibitor," commented Mr. CSN Murthy, Chief Executive Officer of Aurigene. "Based on these initial clinical results, we are excited for the opportunity to expand testing of CA-170, possibly in earlier lines of treatment and in a greater number of immunotherapy treatment-naïve cancer patients." Added Mr. Murthy, "Together with Curis, we have designed a Phase 2 trial in selected populations of patients of interest to be treated at major cancer centers in India. Aurigene's decision to sponsor and fund this trial is further affirmation of our commitment to CA-170 and a reflection of the successful collaboration we have with Curis in multiple development programs."

CA-170 is an oral small molecule targeting the immune checkpoints PDL1 and VISTA. Data presented at the ESMO 2017 conference represent the initial 34 patients treated to date in the dose escalation Phase 1 trial. 30 patients were naïve to prior immunotherapy treatment, while four patients had experienced prior treatment with approved anti-checkpoint antibodies. No dose limiting toxicities were observed at doses ranging from 50 mg to 800 mg once daily dosing examined thus far. CA-170 demonstrated good oral bioavailability and plasma drug levels were shown to increase in a near-linear manner with increasing doses. Evidence of immune modulation, including an increase in activated CD8+ T cells, was observed in patient blood and tumor biopsy samples examined following treatment. Of the 21 patients evaluable for disease assessment, 13 patients experienced disease stabilization. Four immunotherapy treatment-naïve patients treated with CA-170 experienced shrinkage of their tumors. Six patients remained on drug treatment beyond three months, including all four patients with tumor shrinkages. In addition, seven of the 34 patients remain on study and are continuing with treatment.

About Curis

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, which 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 PD1 and VISTA pathways, including PDL1/VISTA antagonist CA-170, and oral small molecule antagonists of the PD1 and TIM3 pathways, including PDL1/TIM3 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 myelofibrosis. For more information, visit Curis's 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 with respect to the plans, strategies and objectives of management for future operations, the potential advantages and benefits of CA-170, further plans with respect to the development of CA-170, 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 antagonists for the treatment of patients with cancer, and the Company's plans to advance its development programs, including CA-170. 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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