Curis Announces Dosing of First Patient in a Phase 1 Trial of CA-170, the First Oral Small Molecule Drug Candidate to Target and Inhibit Immune Checkpoints

LEXINGTON, Mass., June 21, 2016 (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 announced that the first patient was dosed in a Phase 1 trial of CA-170.

CA-170 is a first-in-class, orally available, small molecule that is designed to specifically target and inhibit the immune checkpoints, Programmed Death Ligand-1 (PD-L1) and V-domain Immunoglobulin Suppressor of T-cell Activation (VISTA). CA-170 is being developed under a collaboration and licensing agreement with Aurigene Discovery Technologies, Ltd.

"Today, we are pleased to announce dosing of the first patient in our Phase 1 trial of CA-170," said Ali Fattaey, Ph.D., Curis's president and CEO. "During the dose escalation stage of the trial, we look to characterize CA-170's safety and activity in patients with solid tumors and lymphoma. In the expansion stage of the trial, we expect to identify specific indications and regulatory paths for this highly differentiated drug candidate."

Preclinical *ex vivo* experiments demonstrated that CA-170 induced effective proliferation and cytokine production by T cells that are specifically suppressed by PD-L1 or VISTA. In subsequent preclinical *in vivo* studies, CA-170 showed significant anti-tumor activity, similar to anti-PD-1 antibodies, in multiple tumor models.

In preclinical toxicology studies, CA-170 was considered to be safe when administered at multiple dose levels using a once daily oral dosing schedule.

The Phase 1 study is designed to: (1) evaluate the safety, tolerability, and pharmacokinetic profile of CA-170; (2) identify any dose-limiting toxicities; and (3) establish the recommended Phase 2 dose (RP2D) of CA-170 in patients with advanced solid tumors or lymphoma. During the expansion stage, the study is expected to assess the anti-cancer activity of CA-170 at the RP2D in patients with specified cancer types.

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 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, as well as to molecules designed to inhibit the IRAK4 kinase, 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 potential advantages and benefits of small molecule checkpoint inhibitors. 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. Curis Royalty may not receive sufficient levels of royalty revenue from sales of Erivedge to satisfy its royalty-collateralized debt obligation or may otherwise lose its rights to Erivedge 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 also faces risks relating to: potential adverse decisions made by the FDA and other regulatory authorities, investigational review boards, and publication review bodies; competition; its ability to obtain or maintain necessary patent protection; unstable market and economic conditions; unplanned expenses; and 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 March 31, 2016 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'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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