Curis Announces New Preclinical Data for CI-8993 at the Society for Immunotherapy of Cancer (SITC) Annual Meeting

LEXINGTON, Mass., Nov. 9, 2021 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today announced a poster presentation with new preclinical data for CI-8993, a first-in-class monoclonal antibody VISTA antagonist, at the Society for Immunotherapy of Cancer's 36^{th} Annual Meeting.

The investigational product CI-8993 is a fully human $IgG1_K$ monoclonal antibody that binds specifically to this immune checkpoint molecule. To assist in determining the pharmacokinetics and biodistribution of CI-8993 in patients, Dr. Fiona Scott, in collaboration with Prof. Andrew Scott, both of the Olivia Newton-John Cancer Research Institute, conducted a study aimed to develop a Zirconium-89 (^{89}Zr)-labelled CI-8993 for PET (positron-emission tomography) imaging and quantitation, and to validate in preclinical models prior to a planned human trial.

Biodistribution was assessed by image analyses, and tissue counting, with IHC analyses performed to verify VISTA antigen expression. The abstract concluded that the study has validated ^{89}Zr-Df-CI-8993 for specific binding to huVISTA in-vivo. A clinical trial of ^{89}Zr-Df-CI-8993 is planned in solid tumor patients.

"We are pleased to work with the Olivia Newton-John Cancer Research Institute to further our understanding CI-8993 and VISTA biology. These findings further expand the strong foundation of preclinical data supporting CI-8993 and bring us one step closer to delivering on the promise of anti-VISTA therapy for patients with solid tumors," said James Dentzer, President and Chief Executive Officer of Curis.

Details of the presentation are as follows:
Title: Preclinical evaluation of anti-VISTA antibody CI-8993 in a syngeneic huVISTA-KI model
Presenting Author: Andrew M. Scott, MD Olivia Newton-John Cancer Research Institute, Tumour Targeting Laboratory, Melbourne, VIC, Australia
Abstract Number: 324
Abstracts will be available Tuesday, November 9, 2021, at 8:00 a.m.
Virtual ePoster presentations will be available Friday, November 12, 2021, at 7:00 a.m.

Additional meeting information can be found on the SITC website at:
https://www.sitcancer.org/2021/home.

The presentations will also be available under "Posters and Presentations" in the Pipeline: CI-8993 section of the Company's website at www.curis.com

About Curis, Inc.
Curis is a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer. In 2015, Curis entered into a 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 immune checkpoints including the VISTA/PDL1 antagonist CA-170, and the TIM3/PDL1 antagonist CA-327, as well as the IRAK4 kinase inhibitor, CA-4948. CA-4948 is currently undergoing testing in a Phase 1/2 trial in patients with non-Hodgkin's lymphoma both as a monotherapy and in combination with BTK inhibitor ibrutinib. Curis is also evaluating CA-4948 in a Phase 1/2 trial in patients with acute myeloid leukemia and myelodysplastic syndromes, for which it has received Orphan Drug Designation from the U.S. Food and Drug Administration. In addition, Curis is engaged in a collaboration with ImmuNext for development of CI-8993, a monoclonal anti-VISTA antibody, which is currently undergoing testing in a Phase 1 trial in patients with solid tumors. 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. For more information, visit Curis's website at www.curis.com.

About the Olivia Newton-John Cancer Research Institute
The Olivia Newton-John Cancer Research Institute (ONJCRI) is a leader in the development of experimental and breakthrough cancer treatments. ONJCRI investigates and develops treatments for cancers of the breast, bowel, lung, melanoma, prostate, liver, gastrointestinal tract, and brain. Its researchers and clinicians are actively involved in running clinical trials, giving patients access to potential new treatments including immunotherapies and personalised medicine. For more information visit www.onjcri.org.au.

Forward-Looking Statements:
This press release contains forward-looking statements within the meaning of the U.S. Private Securities

Litigation Reform Act of 1995, including, without limitation, any statements concerning product research, development, clinical trials and studies and commercialization plans, timelines, anticipated results or the therapeutic potential of drug candidates including any statements regarding the activity, safety and tolerability of CI-8993, the reporting of data, and any preclinical findings; and statements of assumptions underlying any of the foregoing. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "intends," "seeks," "estimates," "assumes," "predicts," "projects," "targets," "will," "may," "would," "could," "should," "continue," "potential," "focus," "strategy," "mission," 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 agreements with Aurigene and ImmuNext will continue for their full terms, or the CRADA with NCI, that Curis or its collaborators 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. In connection with its agreement with Oberland Capital, Curis faces risks relating to the transfer and encumbrance of certain royalty and royalty-related payments on commercial sales of Erivedge, including the risk that, in the event of a default by Curis or its wholly-owned subsidiary, Curis could lose all retained rights to future royalty and royalty-related payments, Curis could be required to repurchase such future royalty and royalty-related payments at a price that is a multiple of the payments it has received, and its ability to enter into future arrangements may be inhibited, all of which could have a material adverse effect on its business, financial condition and stock price. Curis will require substantial additional capital to fund its business. If it is not able to obtain sufficient funding, it will be forced to delay, reduce in scope or eliminate some of its research and development programs, including related clinical trials and operating expenses, potentially delaying the time to market for, or preventing the marketing of, any of its product candidates, which could adversely affect its business prospects and its ability to continue operations, and would have a negative impact on its financial condition and its ability to pursue its business strategies. Curis faces substantial competition. Curis and its collaborators face the risk of 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, natural disasters, public health crises, political crises and other events outside of Curis's control could significantly disrupt its operations or the operations of third parties on which Curis depends, and could adversely impact Curis's operating results and its ability to raise capital. For example, the COVID-19 pandemic may result in closures of third-party facilities, impact enrollment in clinical trials or impact sales of Erivedge by Genentech and/or Roche. The extent to which the COVID-19 pandemic may impact Curis's business or operating results is uncertain. Other important factors that may cause or contribute to actual results being materially different from those indicated by forward-looking statements include the factors set forth under the captions "Risk Factor Summary" and "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.

SOURCE Curis, Inc.

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