

Curis Announces New Preclinical Data Highlighting the Potential of CA-4948 in Multiple Hematologic Malignancies Presented at the AACR-NCI-EORTC Virtual Conference on Molecular Targets and Cancer Therapeutics

LEXINGTON, Mass., Oct. 7, 2021 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today announced two poster presentations with new preclinical data for CA-4948, a first-in-class small molecule IRAK4 inhibitor, at the AACR-NCI-EORTC Virtual Conference on Molecular Targets and Cancer Therapeutics.

"In ongoing Phase 1 clinical trials, CA-4948 has already demonstrated anti-tumor activity in non-Hodgkin's lymphoma, acute myeloid leukemia and myelodysplastic syndromes. New preclinical data presented at AACR-NCI-EORTC today support the potential of CA-4948 in additional hematologic cancers," said James Dentzer, President and Chief Executive Officer of Curis.

"Notably, these new preclinical data indicate that CA-4948 is synergistic with small molecules targeting BCR signaling, including both idelalisib and ibrutinib, and suggest it may help overcome or reduce secondary resistance to these therapies in marginal zone lymphoma. In addition, these data demonstrate that CA-4948 can cross the blood brain barrier and improve survival, in a dose-dependent manner, providing additional preclinical support for the study of CA-4948 in patients with primary central nervous system (pCNS) lymphoma, one of the most aggressive forms of lymphoma and a clear area of unmet need for patients." Mr. Dentzer added.

Details of the presentations are as follows:

Title: Pharmacological inhibition of IRAK-4 with CA-4948 is beneficial in marginal zone lymphoma models with secondary resistance to PI3K and BTK inhibitors

Author: Francesca Guidetti, Institute of Oncology Research, Faculty of Biomedical Sciences, USI, Bellinzona, Switzerland

Poster Number: P073

Title: The IRAK4 inhibitor CA-4948 demonstrates antitumor activity in a preclinical model of CNS lymphoma

Author: Christina A. von Roemeling, Ph.D., Research Associate, UF Brain Tumor Immunotherapy Program, Department of Neurosurgery, McKnight Brain Institute, University of Florida

Poster Number: P243

Additional meeting information can be found on the AACR website at:

<https://www.aacr.org/meeting/aacr-nci-eortc-international-conference-on-molecular-targets-and-cancer-therapeutics/program/>.

The presentations will also be available under "Posters and Presentations" in the Pipeline: CA-4948 section of the Company's website at www.curis.com

About CA-4948

CA-4948 is an IRAK4 kinase inhibitor and IRAK4 plays an essential role in the toll-like receptor (TLR) and interleukin-1 receptor (IL-1R) signaling pathways, which are frequently dysregulated in patients with AML and MDS. Third parties have recently discovered that the long form of IRAK4 (IRAK4-L) is oncogenic and preferentially expressed in over half of patients with AML and MDS. The overexpression of IRAK4-L is believed to be driven by a variety of factors, including specific spliceosome mutations such as SF3B1 and U2AF1.

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.

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 CA-4948 and any preclinical findings including potential combinations and indications; 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.

For further information:

Elif McDonald
VP, Investor Relations and Corporate Communications
Curis, Inc.
617-503-6583
emcdonald@curis.com

SOURCE Curis, Inc.

<https://investors.curis.com/2021-10-07-Curis-Announces-New-Preclinical-Data-Highlighting-the-Potential-of-CA-4948-in-Multiple-Hematologic-Malignancies-Presented-at-the-AACR-NCI-EORTC-Virtual-Conference-on-Molecular-Targets-and-Cancer-Therapeutics>