Curis Doses First Patient in Phase 1 Study of CA-4948 in Patients with Acute Myeloid Leukemia and Myelodysplastic Syndromes

- Enrolling patients with spliceosome mutations that drive expression of IRAK4-L -
- Initial data expected in the fourth quarter of 2020 -

LEXINGTON, Mass., July 7, 2020 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today announced that the first patient has been dosed in its Phase 1 trial evaluating CA-4948, a novel, small molecule IRAK4 kinase inhibitor, in patients with acute myeloid leukemia (AML) or high-risk myelodysplastic syndromes (MDS) with spliceosome mutations, such as SF3B1 and U2AF1, that drive expression of the long isoform of IRAK4 (IRAK4-L). IRAK4 plays an essential role in the toll-like receptor (TLR) and interleukin-1 receptor (IL-1R) signaling pathways, and these pathways are frequently dysregulated in patients with AML and MDS.

"When Drs. Daniel Starczynowski, Professor, Cincinnati Children's Hospital and Amit Verma, Director of the Division of Hematologic Malignancies at the Albert Einstein College of Medicine, demonstrated the important pathogenic role of IRAK4 in MDS/AML in their seminal publication in Nature Cell Biology and presentation at ASH last December, everyone in the AML/MDS community paid attention, including our team at Curis," said James Dentzer, President and Chief Executive Officer of Curis. "Dr. Starczynowski, Dr. Verma, and their colleagues showed that IRAK4-L, the oncogenic long isoform of IRAK-4, is expressed as a result of specific spliceosome mutations common in AML and MDS. Further, they demonstrated that it potentially impacts over 50% of the AML/MDS population. We quickly worked with our clinical investigators and the U.S. Food and Drug Administration (FDA) to design a study of CA-4948, our first-in-class IRAK4 inhibitor, in this population. We are pleased to announce today, just six months later, that we have initiated this new study and successfully dosed our first patient. The initial dose in this study is 200mg twice-daily (BID) which, based on our preclinical models, we believe may be a therapeutic dose level. As a result, we expect to report initial efficacy data by the end of the year."

"Historically, no single oncogenic driver of AML and MDS has been known to impact the majority of patients," said DrGuillermo Garcia-Manero, Chief, Section of Myelodysplastic Syndromes at theUniversity of Texas MD Anderson Cancer Center. "Recent studies have changed this understanding. The long isoform of IRAK4, itself the result of specific genetic mutations, was recently discovered to be a driver of disease in over half the population of patients with AML and MDS. With CA-4948, we may now have a single drug that can directly target a key driver of disease in these patients. We are delighted to be a lead clinical site in the study of this novel new drug."

About the CA-4948 Phase 1 Clinical Trial

The Phase 1 trial is an open-label, dose escalation study designed to evaluate the safety, pharmacokinetics, pharmacodynamics and clinical activity of CA-4948 in patients with AML and high-risk MDS. The primary objective of the study is to determine the maximum tolerated dose and recommended Phase 2 dose of CA-4948 based on safety and tolerability, dose-limiting toxicities (DLTs), and pharmacokinetic and pharmacodynamic findings. A minimum of three patients will be enrolled at each dose level, starting with 200 mg BID, which was determined to be safe, capable of achieving relevant levels of drug exposure, and demonstrated signs of biologic activity and clinical efficacy in a separate, ongoing Phase 1 study. Each treatment cycle will be 28 days in length and repeated in the absence of toxicity. Initial data from the study is expected in the fourth quarter of 2020.

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 trial in patients with non-Hodgkin lymphoma and in a Phase 1 trial in patients with acute myeloid leukemia and myelodysplastic syndromes. In addition, Curis is engaged in a collaboration with ImmuNext for development of CI-8993, a monoclonal anti-VISTA antibody. 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' 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, statements regarding the potential advantages and benefits of CA-4948 to treat patients with acute myeloid leukemia (AML) and/or with myeloid malignancies and certain spliceosome mutations, the Company's plans to report initial efficacy data in the fourth quarter of 2020, and the Company's expectations regarding the potential therapeutic benefit of CA-4948. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "intends," "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' 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' 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, 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. Based on its available cash resources, it does not have sufficient cash on hand to support current operations within the next 12 months from the date of this press release. 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. If it is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on its audited financial statements, and it is likely that investors will lose all or a part of their investment. 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, natural disasters, public health crises, political crises and other events outside of Curis' control could significantly disrupt its operations or the operations of third parties on which Curis depends, and could adversely impact Curis' 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 Curis' ongoing or planned clinical trials or impact sales of Erivedge by Genentech and/or Roche. The extent to which the COVID-19 pandemic may impact Curis' business or operating results is uncertain. 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 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' 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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