# Curis Announces First Patient Dosed in Phase 1/2 Study of CA-4948 Combination Therapy in Patients with Relapsed or Refractory Acute Myeloid Leukemia or High-Risk Myelodysplastic Syndromes

**- Initial data expected in 2022 -**

LEXINGTON, Mass., Nov. 8, 2021 /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 the combination therapy portion of the Phase 1/2 clinical study evaluating CA-4948, a novel, small molecule IRAK4 kinase inhibitor, in acute myeloid leukemia (AML) or high-risk myelodysplastic syndromes (MDS).

"We are very pleased to announce the initiation of our Phase 1 combination therapy study of CA-4948, which is an important part of our development strategy to address the broader AML/MDS patient population," said James Dentzer, President and Chief Executive Officer of Curis. "This comes on the heels of the promising initial monotherapy data with CA-4948 in this patient population. Armed with these results and combined with preclinical data highlighting CA-4948's synergistic antitumor activity when used in combination with azacitidine and venetoclax, and the absence of overlapping dose-limiting toxicity, we are hopeful that this combination portion of the trial will allow us to advance CA-4948 as a promising new treatment for an additional population of patients with AML/MDS."

"Based on CA-4948's initial efficacy and tolerability in monotherapy, we are looking forward to exploring safety and efficacy for CA-4948 in combination with azacitidine or venetoclax," said Dr. Stefano Tarantolo, M.D., hematologist and oncologist at Nebraska Cancer Specialists and a leading investigator on the study. "We are hopeful that CA-4948 may offer an important new treatment option, as many of these patients are ineligible for intensive chemotherapy and face an extremely poor prognosis."

**About the CA-4948 Phase 1/2 Study in Patients with AML/MDS**

The Phase 1/2 study was expanded to include both a monotherapy dose expansion and a combination dose escalation. The monotherapy portion of the study includes R/R MDS patients with and without a spliceosome mutation and R/R AML patients with and without a FLT3 mutation. The combination therapy portion of the study includes two arms: CA-4948 plus azacitidine, for patients naïve to HMA, and CA-4948 plus venetoclax, for patients naïve to venetoclax.

When combined with azacitidine, CA-4948 will be dosed at 200 mg twice daily for 21 days of a 28-day cycle, followed by a 300 mg dose cohort if tolerability allows. Azacitidine will be given in 7 consecutive doses or split doses starting at 75 mg/$m^2$.

When combined with venetoclax, CA-4948 will be dosed at 200 mg twice daily for 21 days of a 28-day cycle, followed by a 300 mg cohort if tolerability allows. Venetoclax will be administered at 100 mg orally with a ramp up over 3 days to 400 mg for 21 days of a 28-day cycle.

The primary objective of the combination portion of the study is to determine the recommended Phase 2 dose (RP2D) for CA-4948 in combination with azacitidine and in combination with venetoclax based on safety and tolerability, dose-limiting toxicities (DLT), and any biologic activity, pharmacokinetic and pharmacodynamic findings from the study population. Additional objectives include characterization of CA-4948's pharmacokinetic parameters and overall response rate.

**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, statements regarding any expectations of the potential for the Company's proprietary drug candidate CA-4948, including the potential developments and benefits of CA-4948 in combination with azacitidine or venetoclax, statements with respect to the Company's studies, strategies, commercialization plans, timelines, anticipated results, findings, activity, safety and tolerability of CA-4948 as a monotherapy or in combination, and the Company's ability to advance and broaden its clinical programs. 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 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'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 caption "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.

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

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