Curis Announces Additional Encouraging Clinical Data from TakeAim Leukemia Study of emavusertib (CA-4948) in Monotherapy R/R AML and hrMDS

29% CR rate observed in R/R AML patients with FLT3 mutation

22% CR/CRh rate observed in R/R AML with spliceosome mutation

45% ORR observed in R/R hrMDS patients with spliceosome mutation

Curis to review results during conference call, featuring commentary by Dr. Eric Winer, MD, Dana-Farber Cancer Institute, on Monday, December 12 at 10:00 a.m. ET

LEXINGTON, Mass., Dec. 12, 2022 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today announced positive updated clinical data from the ongoing open label Phase 1a dose escalation study of emavusertib (CA-4948), a novel, small molecule IRAK-4 inhibitor, as a monotherapy in patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) or high risk myelodysplastic syndromes (hrMDS) in both targeted and non-targeted populations. Patients in a targeted population are those with disease harboring U2AF1, SF3B1 (collectively "spliceosome") or FLT3 mutations. The company also announced positive initial data of emavusertib in combination with venetoclax in patients with AML or hrMDS that enrolled in the combination phase (Phase 1b) of the TakeAim Leukemia study prior to the partial clinical hold placed in April 2022.

"We have nearly doubled the size of the targeted patient data set, and continue to see consistent and deep anticancer activity, including additional objective responses. We believe these data suggest a favorable anti-cancer activity compared to therapies currently available for these patients. We are also encouraged by the initial combination data," said James Dentzer, President and Chief Executive Officer of Curis.

As of October 12, 2022, the total monotherapy data to date represents 24 response evaluable patients with a targeted mutation and 34 response evaluable patients without a targeted mutation. This represents 11 additional patients treated in targeted monotherapy populations and 13 additional patients in the non-targeted monotherapy population. In addition to the monotherapy data, there are 4 patients with AML/hrMDS who have been treated with emavusertib in combination with venetoclax.

In Expanded Data Set, Findings Support Earlier Data Presented in June 2021 and January 2022

Previous data presented by Curis highlighted preliminary efficacy data of emavusertib in R/R AML/MDS patients whose disease is characterized by spliceosome or FLT3 mutation. It is this genetically-defined subset of AML/MDS that is specifically targeted by emavusertib and which we believe, represents the patients most likely to benefit from treatment with emavusertib in monotherapy. Today's clinical data update provides an expanded data set for this genetically-defined patient population.

In targeted AML patient monotherapy populations key findings included:

- Patients with a FLT3 mutation had a CR (complete remission) rate of 29% (2 of 7 patients);
  - In addition to the 2 patients who achieved CRs, a 3rd patient achieved MLFS (morphologic leukemia-free state), and a 4th patient with gilteritinib-refractory disease achieved near normalization of blast count and complete loss of detectable FLT3 clone
- Patients with a spliceosome mutation had CR/CRh rate of 22% (2 of 9 patients)

In targeted hrMDS patient monotherapy populations key findings included:

- ORR (objective response rate) of 45% (5 of 11 patients)
- All 5 responses achieved a marrow CR (mCR)

In combination AML/hrMDS patient populations key findings included:

- ORR of 50% (2 of 4 patients)
- Both responses achieved mCR

These data continue to confirm the earlier data that emavusertib provides favorable anti-cancer activity in AML and hrMDS patients with a spliceosome and/or FLT3 mutation. Further, anti-cancer activity in non-targeted

patients as well as in combination with venetoclax suggest potential for incremental efficacy in combination with existing therapies. We are continuing to enroll patients at the 200mg dose level and plan to discuss with the U.S. Food and Drug Administration (FDA) a recommended phase 2 dose in mid-2023.

Conference Call Information

Curis management will host a conference call today, December 12, 2022 at 10:00 a.m. ET, to discuss the results with Dr. Eric Winer, Clinical Investigator at the Dana-Farber Cancer Institute. To access the live call, please dial (888) 346-6389 from the United States or (412) 317-5252 from other locations, shortly before 10:00 a.m. ET. A live webcast will be available under "Events & Presentations" in the Investors section of the Company's website at www.curis.com. A replay of the webcast will be available on the Curis website shortly after completion of the call.

About emavusertib (CA-4948)

Emavusertib 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 cancer. TLRs and the IL-1R family signal through the adaptor protein MYD88, which results in the assembly and activation of IRAK4, initiating a signaling cascade that induces cytokine and survival factor expression mediated by the NF-κB protein complex. Additionally, 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 mutation such as SF3B1 and U2AF1. In addition to inhibiting IRAK4, emavusertib was also designed to inhibit FLT3, a known oncologic driver, which may provide additional benefit in patients with AML and MDS.

About TakeAim Studies

TakeAim Leukemia Study (NCT04278768) - This study is only enrolling in the monotherapy dose finding phase (phase 1a) of the study. The partial hold remains in place for the combination therapy phase (phase 1b) and expansion phase (phase 2a) of the study.

TakeAim Lymphoma Study (NCT03328078) – This study is open for enrollment.

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, emavusertib (CA-4948). Emavusertib is currently undergoing testing in the Phase 1/2 TakeAim Lymphoma trial in patients with hematologic malignancies, such as non-Hodgkin's lymphoma and other B cell malignancies, both as a monotherapy and in combination with BTK inhibitor ibrutinib, and the Phase 1/2 TakeAim Leukemia trial in patients with acute myeloid leukemia and myelodysplastic syndrome, for which it has received Orphan Drug Designation from the U.S. Food and Drug Administration. The FDA has placed a partial clinical hold on the TakeAim Leukemia trial during which no new patients will be enrolled in the monotherapy expansion phase (Phase 2a) or the combination phase (Phase 1b) of emavusertib with azacitidine or venetoclax, and current study participants benefiting from treatment may continue to be treated with emavusertib at doses of 300mg BID or lower. 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's website at www.curis.com.

Cautionary Note Regarding 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 with respect to Curis's plans, strategies and objectives to further patient enrollment in the monotherapy dose escalation phase (Phase 1a) of the TakeAim Leukemia trial, its ability to resolve the remaining partial clinical hold on the combination therapy phase (Phase 1b) and the expansion phase (Phase 2a) of the TakeAim Leukemia study, and its plans to discuss with the FDA a recommended phase 2 dose in mid-2023, 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 initiation, progression, expansion, use, safety, efficacy, dosage and potential benefits of emavusertib in clinical trials as a monotherapy and/or as a combination therapy, Curis's plans and timelines to provide preliminary, interim and/or additional

data from its ongoing or planned clinical trials, any statements concerning Curis's expectations regarding its interactions with the FDA, statements with respect to mutations or potential biomarkers, 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, the FDA may not remove the remaining partial clinical hold on the combination therapy phase (Phase 1b) and the expansion phase (Phase 2a) of TakeAim Leukemia trial, or may take further regulatory action with regard to such trial. 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 basal cell carcinoma (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.

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