Curis Announces FDA Partial Clinical Hold for TakeAim Leukemia Study of Emavusertib (CA-4948)

LEXINGTON, Mass., April 4, 2022 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today announced that the U.S. Food and Drug Administration (FDA) has placed a partial clinical hold on the Company's TakeAim Leukemia Phase 1/2a study (NCT04278768). The TakeAim Leukemia study is a Phase 1/2a open-label, single arm dose escalation and expansion study of orally-administered emavusertib (CA-4948) as monotherapy and in combination with azacitidine or venetoclax in patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) or high-risk myelodysplastic syndrome (MDS).

While the partial hold is in place, no new patients will be enrolled in the study, and current study participants benefitting from treatment may continue to be treated with emavusertib at doses of 300mg BID or lower.

With the partial hold, the FDA is requesting additional data from the study, including data related to the death of a R/R AML patient who experienced, among several conditions, rhabdomyolysis, which has previously been identified as a dose-limiting toxicity of emavusertib. Additionally, the FDA is requesting safety, efficacy, and other data, including data related to rhabdomyolysis and the Company's determination of the Recommended Phase 2 Dose for emavusertib in this study.

"We are committed to ensuring the safety of patients in our studies and to working collaboratively with the FDA to develop therapies that meaningfully improve and extend patients' lives," said James Dentzer, Chief Executive Officer of Curis. "Given the clinical profile of emavusertib observed to date, we are hopeful that the study can be resumed soon, after appropriate review. We continue to be confident in the potential of emavusertib to address the high unmet need of patients with AML or MDS."

Curis expects to provide updated guidance on the timing of discussing the potential for a rapid registrational path for emavusertib with the FDA after the partial clinical hold is resolved and the related impact on the trial can be determined.

While this partial hold does not affect the TakeAim Lymphoma study (NCT03328078), a Phase 1/2 open-label dose escalating clinical trial investigating emavusertib in patients with B-cell malignancies, the Company has decided to pause enrollment of new patients in that study as well, pending resolution of the partial clinical hold in the TakeAim Leukemia study.

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 B-cell malignancies, both as a monotherapy and in combination with BTK inhibitor ibrutinib. The FDA has placed a partial clinical hold on Curis's evaluation of emavusertib in the Phase 1/2 TakeAim Leukemia 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.

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 concerning Curis's expectations regarding its interactions with the FDA, its ability to resolve the partial clinical hold of the TakeAim Leukemia study, and Curis's plans to advance its development programs for emavusertib, including with respect to anticipated results, clinical trials, regulatory plans and timelines; 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 partial clinical hold on the Phase 1/2 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, or the CRADA with NCI, 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. 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 the factors that are discussed in other filings that we periodically make with the Securities and Exchange Commission. 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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