FDA Allows Patient Enrollment to Resume in Monotherapy Dose Escalation of Emavusertib in TakeAim Leukemia Study

Curis working with clinical sites to resume enrollment

Preliminary clinical data update expected in 2023

LEXINGTON, Mass., Aug. 30, 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 notified Curis that it may resume enrollment of additional patients in the monotherapy phase of the TakeAim Leukemia study.

Previously, Curis announced that the FDA had placed partial clinical holds on the TakeAim Leukemia and TakeAim Lymphoma studies in April 2022. On August 18, 2022, Curis reported that the partial clinical hold on the TakeAim Lymphoma study was lifted. After review of the comprehensive data package submitted by Curis, the FDA has notified Curis that it may resume enrollment of additional patients in the monotherapy dose finding phase (Phase 1a) of the TakeAim Leukemia study, in which the company has agreed to enroll at least nine additional patients at the 200mg dose level. The partial hold remains in place for the combination therapy phase (Phase 1b) and the expansion phase (Phase 2a) of the study until Phase 1a is complete and the FDA approves proceeding to the next phases of the study.

Before lifting the restriction on patient enrollment, the FDA reviewed additional data provided by the company related to the risk of rhabdomyolysis, a side effect also associated with statins, as well as with cancer medications such as Odomzo® and Cotellic®. The FDA also reviewed the company's strategy for utilizing objective laboratory measurements, similar to those used with Odomzo and Cotellic, to identify rhabdomyolysis, as well as the company's strategy for managing rhabdomyolysis, if it is detected.

"We are pleased to announce the results of the FDA's review and to have addressed potential concerns about the identification and management of rhabdomyolysis," said James Dentzer, President and Chief Executive Officer of Curis. "We are working with our clinical sites to quickly resume enrollment of additional patients."

Similar to the TakeAim Lymphoma study, the Company is updating its timeline for clinical data release to reflect the availability of updated preliminary data from the TakeAim Leukemia study in 2023. In addition, Curis is proactively discussing the clinical plans for emavusertib in leukemia, including alignment on optimal dose and development path, with the FDA's leukemia division.

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 acute myeloid leukemia (AML) and myelodysplastic syndrome (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. 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 Leukemia

The TakeAim Leukemia study (NCT04278768) is a Phase 1/2 open-label dose escalation, dose expansion clinical trial investigating emavusertib as a monotherapy and in combination with azacitidine or venetoclax in patients with relapsed or refractory (R/R) AML or high risk MDS. After dose escalation in monotherapy to determine the recommended Phase 2 dose (RP2D) and assuming the partial hold for the phase 1b cohort dose escalation in combination to determine the RP2D is lifted, we plan to expand five cohorts: monotherapy in AML patients with spliceosome and FLT3 mutations, monotherapy in patients with MDS and spliceosome mutations and combination therapy with azacitidine or venetoclax in patients without spliceosome or FLT3 mutations. The goals of the study are to determine several parameters including safety, maximum tolerated dose (MTD), RP2D and signals of activity.

About TakeAim Lymphoma

The TakeAim Lymphoma study (NCT03328078) is a Phase 1/2 open-label, dose escalation, dose expansion clinical trial investigating emavusertib as monotherapy and in combination with ibrutinib in patients with R/R hematologic malignancies, such as non-Hodgkin's lymphoma and other B cell malignancies. After dose escalation in both monotherapy and combination therapy

to determine the RP2D, we plan to expand four cohorts for combination treatment: marginal zone lymphoma, activated b-cell diffuse large b-cell lymphoma, primary CNS lymphoma, and patients developing adaptive resistance to ibrutinib monotherapy. The goals of the study are to determine several parameters including safety, MTD, RP2D and signals of activity.

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 AML and MDS, 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 combination phase (Phase 1b) of emavusertib with azacitidine or venetoclax and expansion phase (Phase 2a), 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, 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 atwww.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 resume and further patient enrollment in its TakeAim Lymphoma trial and in the monotherapy dose escalation phase (Phase 1a) of the TakeAim Leukemia trial, and 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, 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.

SOURCE Curis, Inc.

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