Curis Presented Clinical Data from the TakeAim Leukemia Study at the 2023 ASH Conference

LEXINGTON, Mass., Dec. 11, 2023 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of emavusertib (CA-4948), an orally available, small molecule IRAK4 inhibitor, last night presented clinical data from its TakeAim Leukemia Study at the 2023 ASH Conference.

"We continue to be pleased with patient enrollment in the TakeAim Leukemia study and are especially pleased that the data confirm our observations to date – that emavusertib demonstrates a safe and manageable safety profile in addition to clear anti-cancer activity," said James Dentzer, President and Chief Executive Officer of Curis.

Data were presented for 92 patients treated with emavusertib monotherapy at doses ranging from 200 mg to 500 mg BID. Substantial reductions in blast counts were observed across all patient groups, irrespective of dose level, mutation status, or prior treatment history. Treatment-related adverse events (TRAEs) of grade ≥ 3 were found to be both manageable and acceptable, with no dose-limiting myelosuppression detected.

In the targeted population of patients with a FLT3 mutation, evidence of clear anti-cancer activity included changes in mutational profiles that suggest disease-modifying activity. These results were observed in patients including those who had progressed on a prior FLT3 inhibitor.

Among relapsed/refractory patients with FLT3 mutation who received ≤ 2 prior lines of treatment and had both baseline and post-treatment marrow evaluations, administering 300 mg emavusertib BID yielded compelling results. Notably, 2 out of 3 patients achieved a Complete Response (CR) with the other achieving morphological leukemia free state, indicating strong activity in patients with FLT3 mutation.

About emavusertib (CA-4948)

Emavusertib is a small molecule IRAK4 inhibitor. 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. Preclinical studies targeting IRAK1/4 in combination with FLT3 have demonstrated the ability to overcome the adaptive resistance incurred when targeting FLT3 alone. Further, emavusertib has shown anti-tumor activity across a broad range of hematologic malignancies including monotherapy activity in patient-derived xenografts and synergy with both azacitidine and venetoclax.

About TakeAim Leukemia Study

TakeAim Leukemia Study (NCT04278768) – study is open for enrollment.

About Curis, Inc.

Curis is a biotechnology company focused on the development of emavusertib, an orally available, small molecule IRAK4 inhibitor. Emavusertib is currently undergoing testing in the Phase 1/2 TakeAim Lymphoma study in patients with hematologic malignancies, such as non-Hodgkin's lymphoma and other B cell malignancies in combination with the BTK inhibitor ibrutinib, and as a monotherapy in the Phase 1/2 TakeAim Leukemia study 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. Curis, through its 2015 collaboration with Aurigene, has the exclusive license to emavusertib (CA-4948). Curis licensed its rights to Erivedge® to Genentech, a member of the Roche Group, under which they 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 the TakeAim Leukemia study including the activity, safety, tolerability, manageability and efficacy of emavusertib. 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. 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 agreement with Aurigene will continue for its full term, 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 commercialize Erivedge in basal cell carcinoma. 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. 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. 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.

For further information: For further information: Investor Relations, Stephanie Ascher, Stern Investor Relations, Inc (212) 362-1200, stephanie.ascher@sternir.com

---

https://investors.curis.com/2023-12-11-Curis-Presented-Clinical-Data-from-the-TakeAim-Leukemia-Study-at-the-2023-ASH-Conference