

## Curis Announces Additional Data from TakeAim Leukemia Study

LEXINGTON, Mass., Dec. 10, 2024 /PRNewswire/ -- Curis, Inc. ("Curis") (NASDAQ: CRIS), a biotechnology company focused on the development of emavusertib (CA-4948), an orally available, small molecule IRAK4 inhibitor, yesterday presented data from the TakeAim Leukemia study (CA-4948-102) in relapsed/refractory (R/R) Acute Myeloid Leukemia (AML) at the 66<sup>th</sup> ASH annual meeting.

The additional data presented include data for 21 patients with a FLT3 mutation (FLT3m) who had received fewer than 3 lines of prior therapy and were treated with emavusertib as monotherapy at the Recommended Phase 2 Dose (RP2D) of 300 mg BID. This brings the total number of patients dosed at the RP2D from 12 to 21 patients.

Data show 10 objective responses in 19 response-evaluable patients: 6 complete remission (CR), 2 CR with either a complete remission with incomplete hematological recovery (CRi) or a partial hematological recovery (CRh) and 2 morphologic leukemia-free state (MLFS). Prior therapies of responders included Venetoclax (5/10), HMA (6/10), and FLT3i (6/10). Two of the 21 patients were treated, but discontinued treatment prior to first disease assessment (death occurred at Day 8 and Day 13, respectively), and were not included as response-evaluable patients.

Two patients who achieved a CR and CRi, respectively, proceeded to allogeneic stem cell transplantation. Responses were achieved rapidly in this population, with 7 of 10 responses reported at the first assessment (Cycle 2 Day 1).

"We continue to be pleased with the monotherapy data in R/R AML patients with a FLT3 mutation," said James Dentzer, President and CEO of Curis, "and believe these data further support the exciting potential of emavusertib's novel mechanism to address a significant unmet need in patients with AML."

### 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 (CA-4948-101) in patients with relapsed/refractory primary central nervous system lymphoma (PCNSL) in combination with the BTK inhibitor ibrutinib, as a monotherapy in the Phase 1/2 TakeAim Leukemia study (CA-4948-102) in patients with relapsed/refractory acute myeloid leukemia (AML) and relapsed/refractory high risk myelodysplastic syndrome (hrMDS) with either a FLT3 mutation or a splicing factor mutation (U2AF1 or SF3B2), and as a frontline combination therapy with azacitidine and venetoclax in patents with AML (CA-4948-104). Emavusertib has received Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of AML and MDS and from the European Commission for the treatment of PCNSL. 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](http://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, statements regarding additional data from the TakeAim Leukemia study and the therapeutic potential of emavusertib in patients with AML; statements concerning research, development, clinical trials and commercialization plans, timelines, anticipated results or the therapeutic potential of emavusertib including the progression, expansion, use, safety, efficacy, rates and duration of responses, mutations or potential biomarkers, and potential benefits of emavusertib in clinical trials as a monotherapy and/or as a combination therapy; 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. 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. Curis is dependent on the success of emavusertib and any delays in the development of emavusertib could have a material adverse effect on its business. 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. Based on its available cash resources, it does not have sufficient cash on hand to support current operations within the next 12 months from the date of this press release. If it is not able to obtain sufficient funding, it will be forced to delay, reduce in scope or eliminate the development of emavusertib, including related clinical trials and operating expenses, potentially delaying the time to market for, or preventing the marketing of, emavusertib, 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.

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