Curis Announces Additional Data from TakeAim Leukemia Study

Data update expands AML dataset from 5 to 30 patients

LEXINGTON, Mass., May 14, 2024 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of emavusertib (CA-4948), an orally available, small molecule IRAK4 inhibitor, today announced updated data from the ongoing TakeAim Leukemia study (CA-4948-102) in relapsed/refractory (R/R) AML to be presented at the ASCO and EHA conferences.

This update includes data for 25 new patients in the FLT3 mutation (FLT3m) and U2AF1/SF3B1 Splicing Factor mutation (SFm) cohorts 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.

	Prior Data	New Data*	Total
FLT3m AML	3	9	12
SFm AML	3	17	20
adjustment for patients with dual mutation**	(1)	(1)	(2)
	5	25	30

** data cut-off as of February 26, 2024*

*** 2 patients had both FLT3m and SFm (dual mutation)*
1 patient in the initial group of 5 patients; 1 patient in the new group of 25 additional patients

FLT3m Cohort – 12 relapsed/refractory patients enrolled to date

12 R/R AML patients with FLT3m were treated with emavusertib. Prior therapies included venetoclax (8/12), hypomethylating agents or HMA (9/12), and FLT3 inhibitors (9/12). Preliminary data show 6 objective responses in 11 response-evaluable patients: 3 complete remission (CR), 1 CR with partial hematologic recovery (CRh) and 2 morphologic leukemia-free state (MLFS) with on-treatment duration range of 46-324 days. 4 patients are ongoing at the data-cutoff, including 1 CRh and 1 MLFS.

- 3 of 3 patients who were naïve to FLT3i treatment achieved objective response (2 CR, 1 MLFS)
- 3 of 8 patients who progressed on, or following, prior FLT3i treatment achieved objective response (1 CR, 1 CRh, 1 MLFS)
- 1 patient is not response-evaluable

All responders demonstrated complete normalization of blast counts in the bone marrow. One of these patients proceeded to allogenic stem cell transplantation. Responses were achieved rapidly in this population, with 5 of 6 responses occurring within one cycle of treatment.

SFm Cohort – 20 relapsed/refractory patients enrolled to date

20 R/R AML patients with SFm were treated with emavusertib. Prior therapies included venetoclax (18/20) and HMA (17/20). Preliminary data show 4 of 18 response-evaluable patients in this population have achieved objective response (CR/CRh/MLFS). 8 of 20 patients are ongoing at the data-cutoff, including 1 MLFS and 3 non-responding patients who have shown increased neutrophil counts.

- All 4 responders (1 CR, 2 CRh, 1 MLFS) had received prior treatment with an HMA; 3 of whom had also received prior treatment with venetoclax
- 3 additional non-responding patients are ongoing and have shown increased neutrophil counts
- 2 patients are not response-evaluable

All responders demonstrated complete normalization of blast counts in the bone marrow. One of these patients proceeded to allogenic stem cell transplantation. "In addition to the responders, we see increased neutrophil counts in several additional ongoing patients. Since a leading cause of death in patients with AML is infection (related to low neutrophil counts), an increase in neutrophils represents a meaningful clinical improvement for these patients," said Dr. Robert Martell, MD, PhD, Chief Scientific Officer of Curis.

"We are encouraged by emavusertib's continued demonstration of clear single-agent activity supporting its potential in both monotherapy and combination therapy in AML," said James Dentzer, President and CEO of Curis.

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 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 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. Emavusertib has received Orphan Drug Designation from the U.S. Food and Drug Administration for the treatment of AML and MDS. 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 Curis's plans, strategies and objectives for emavusertib, its clinical trials and studies, commercialization plans, timelines, anticipated results or therapeutic potential, 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, its ability to further patient enrollment in its TakeAim Lymphoma, TakeAim Leukemia and AML triplet studies, 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. 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 depends heavily 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 its 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.

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