

## Curis Reports Updated Data in Two Abstracts for CA-4948 Accepted for Presentation at the European Hematology Association 2021 Virtual Congress

- Updated clinical data from Phase 1/2 study of CA-4948 in acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) from February data-cut includes reduction of marrow blasts in 8 out of 9 evaluable patients with elevated blast counts at baseline -
- Four objective responses observed, including 1 complete response (CR), 1 complete remission with incomplete hematologic recovery (CRi) with negative minimal residual disease, and 2 bone marrow CRs -
- All 3 patients with SF3B1 or U2AF1 spliceosome mutation achieved marrow CR or better -
- CA-4948 demonstrated synergistic antileukemic activity in combination with venetoclax and azacitidine in AML cell lines -
- Additional data to be presented in oral presentation and poster session at the European Hematology Association 2021 Virtual Congress (EHA); along with company-hosted virtual KOL event on June 11, 2021 -

LEXINGTON, Mass., May 12, 2021 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today announced that two abstracts for CA-4948, a novel, small molecule IRAK4 inhibitor, have been accepted for oral and poster presentation at the European Hematology Association 2021 Virtual Congress (EHA), which will be held virtually from June 9-17, 2021. The abstracts include updated data from a February data-cut for its ongoing open-label, single arm, Phase 1/2 study of CA-4948 in patients with acute myeloid leukemia (AML) or high-risk myelodysplastic syndromes (MDS).

"We are very pleased to report this clinical update on our first-in-class IRAK4 kinase inhibitor, CA-4948, as an anticancer agent for patients with acute myeloid leukemia and myelodysplastic syndromes for whom multiple prior lines of therapy have been unsuccessful," said James Dentzer, President and Chief Executive Officer of Curis. "The clinical data published in the abstract this morning are consistent with our preliminary findings reported late last year showing that CA-4948 has, in addition to encouraging safety characteristics, clear potential to reduce leukemic blasts in late-line patients, along with early signs of hematologic recovery. We look forward to providing updated safety, pharmacodynamic, and efficacy data, as well as data from additional patients and nonclinical combination synergy data at EHA next month."

Key findings from a cutoff date of February 8, 2021 in 15 patients (8 MDS and 7 AML) include:

- Bone marrow blast reductions observed at all tested doses in 8 of 9 (89%) evaluable patients (at least one malignancy assessment following first cycle) with elevated blast counts at baseline
- Objective responses observed included 1 patient experiencing a full hematologic recovery complete response, 1 CRi with negative minimal residual disease, and 2 bone marrow CRs
- All 3 patients with SF3B1 or U2AF1 spliceosome mutation achieved marrow CR or better
- All patients with objective responses also saw signs of hematologic recovery

Details of the presentations are as follows:

### Oral Presentation:

**Title:** A Phase 1, Dose Escalation Trial with Novel Oral IRAK4 Inhibitor CA-4948 in Patients with Acute Myelogenous Leukemia or Myelodysplastic Syndrome – Interim Report

**Author:** Guillermo Garcia-Manero, MD, *MD Anderson Cancer Center*

**Session Name:** 10. Myelodysplastic syndromes - Clinical

**Presentation Time:** Friday, June 11, 2021, 09:00 CEST (3:00 am ET)

**Q&A Session:** Wednesday, June 16, 2021, 17:00 CEST (11:00 am ET)

### Poster Presentation

**Title:** IRAK4 Inhibitor CA-4948 Potentiates Antitumor Effects of Azacitidine and Venetoclax in Human Acute Myeloid Leukemia

**Session Name:** 01. Acute lymphoblastic leukemia – Biology & Translational Research

**Session Date & Time:** Friday, June 11, 2021, 09:00 CEST (3:00 am ET)

### Virtual KOL Event

Virtual event to be hosted Friday, June 11 at 8:00 am ET, featuring Dr. Guillermo Garcia-Manero, Chief of the Section of Myelodysplastic Syndromes within the Department of Leukemia at The University of Texas MD Anderson Cancer Center. Discussion of the EHA presentation data from the ongoing Phase 1/2 study of CA-4948 in patients with acute myeloid leukemia and myelodysplastic syndromes.

A live webcast of the presentation will be available under "Events & Presentations" in the Investors section of the Company's website at [www.curis.com](http://www.curis.com). A replay of the webcast will be available on the Curis website for 90 days following

the event.

Additional meeting information can be found on the EHA website at [www.ehaweb.org/congress](http://www.ehaweb.org/congress). Each presentation will also be available under "Events and Presentations" in the Investors section of the Company's website at [www.curis.com](http://www.curis.com)

### **About CA-4948**

CA-4948 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 AML and MDS. Third parties have recently discovered that the long form of IRAK4 (IRAK4-L) is oncogenic and preferentially expressed in over half of patients with AML and 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.

### **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, CA-4948. CA-4948 is currently undergoing testing in a Phase 1/2 in patients with non-Hodgkin's lymphoma both as a monotherapy and in combination with BTK inhibitor ibrutinib. Curis is also evaluating CA-4948 in a Phase 1/2 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' website at [www.curis.com](http://www.curis.com).

### **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, objectives or financial results; 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 activity, durability and tolerability of CA-4948 and any key findings, and statements with respect to 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, 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 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.

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

---

<https://investors.curis.com/2021-05-12-Curis-Reports-Updated-Data-in-Two-Abstracts-for-CA-4948-Accepted-for-Presentation-at-the-European-Hematology-Association-2021-Virtual-Congress>