Curis Announces Updated Data with Additional Encouraging Clinical Activity in Phase 1/2 Study of CA-4948 Monotherapy in Targeted Patients with Relapsed or Refractory AML and MDS; and Initial Clinical Data from Phase 1 Study of CI-8993 in Patients with Relapsed or Refractory Solid Tumors

40% CR/CRh rate (complete remission and complete remission with partial hematologic recovery) in R/R AML patients with U2AF1 or SF3B1 spliceosome mutation treated with CA-4948
57% ORR (objective response rate) observed in R/R MDS patients with U2AF1 or SF3B1 spliceosome mutation treated with CA-4948
Added potential benefit of FLT3 inhibition highlighted by significant marrow blast reduction and eradication of FLT3 mutation in 2 out of 3 R/R AML patients with FLT3 mutation at baseline following treatment with CA-4948
Promising initial safety data of CI-8993 highlights effectiveness of procedures implemented to manage expected cytokine release syndrome and enable dose escalation past 0.3 mg/kg
Pharmacodynamic data provide early indication that targeting VISTA with CI-8993 may activate multiple anti-cancer mechanisms
Management to host conference call today at 8:00 a.m. ET

LEXINGTON, Mass., Jan. 6, 2022 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today announced positive updated clinical data from the ongoing open label Phase 1/2 dose escalation and expansion study of CA-4948, a novel, small molecule IRAK-4 inhibitor, as a monotherapy in patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) or high risk myelodysplastic syndromes (MDS) as well as initial safety, pharmacokinetic and pharmacodynamic data from the Phase 1 dose escalation study of CI-8993, a monoclonal antibody targeting VISTA for patients with R/R solid tumors.

"These data continue to build on what we believe to be a compelling profile for CA-4948, showing its activity as a monotherapy in a targeted population of patients living with R/R AML/MDS, for whom prior lines of therapy have been unsuccessful," said James Dentzer, President and Chief Executive Officer of Curis. "We are especially pleased that these results demonstrate both a favorable safety profile and improved anti-cancer activity compared with standard of care therapies for these patients. Furthermore, we have been able to successfully identify and enroll these patients using existing genetic diagnostic panels. We remain on track to enroll additional patients with a spliceosome mutation to prepare for potential discussions with the U.S. Food and Drug Administration (FDA) in the first half of 2022 regarding the potential for a rapid registrational path forward for CA-4948 as a monotherapy in genetically-defined patient populations."

"We are also encouraged by the safety data from the CI-8993 trial, which we believe demonstrate that the procedures we implemented to manage the expected cytokine release effect have been successful – and have allowed us to escalate patient dosing up to and beyond 0.3 mg/kg," he continued. "We have recently begun dosing at 0.6 mg/kg; and look forward to providing another update on our progress in the second half of 2022. We are thrilled to have achieved this key safety and dose escalation milestone, as it brings us one step closer to providing anti-VISTA therapy for patients living with solid tumors."

Phase 1/2 monotherapy study of CA-4948 in R/R AML/MDS

Well Tolerated and Manageable Safety Profile at 300 mg BID Dose Level

As of December 16, 2021, 49 total patients had been administered CA-4948 in the R/R AML/MDS study across 200mg, 300mg, 400mg, and 500mg dose cohorts. The safety profile observed to date showed the following key findings:

- CA-4948 was well-tolerated across multiple dose levels, including at the Recommended Phase 2 Dose of 300 mg BID
- Treatment-related adverse events were reversible and manageable
- No dose-limiting myelosuppression
- No cumulative toxicities observed
- No grade 4 or 5 treatment-related adverse events

We believe these attributes of CA-4948's emerging safety profile may provide an advantage compared to current standard of care therapies in monotherapy and could also make CA-4948 an attractive candidate for addition to combination therapy regimens.

In Expanded Data Set, Findings Support Earlier Data Presented inJune 2021

Previous data presented by Curis at the European Hematology Association inJune 2021, highlighted preliminary efficacy data of CA-4948 in R/R AML/MDS patients whose disease is characterized by spliceosome or FLT3 mutation. It is this genetically-defined subset of AML/MDS that is specifically targeted by CA-4948 and therefore represents the patients most likely to benefit from treatment with CA-4948 in monotherapy. Today's clinical data update provides an expanded data set for this genetically-defined patient population and further support the rationale for seeking a discussion with FDA in the first half of 2022 to discuss the potential for a rapid registrational path forward for CA-4948 as a monotherapy in genetically-defined patient populations.

In order to assess preliminary efficacy for these patients on study, Curis presented data on patients that had enrolled as of September 30, 2021, which allowed the opportunity for at least 2 disease assessments, to determine marrow response. Based on this criterion, there were 12 evaluable patients with a U2AF1 or SF3B1 spliceosome mutation (7 MDS; 5 AML) and 3 evaluable patients with a FLT3 mutation. There were 13 total evaluable patients; two AML patients presented with both a spliceosome mutation and FLT3 mutation and are therefore included in both subpopulations. These patients had experienced a median of 2 prior lines of therapy (range 1-4), and all patients had prior hypomethylating agent (HMA) treatment.

In patients with spliceosome-mutated R/R AML, key findings included:

- CR/CRh rate of 40% (2 out of 5 patients)
- Both patients who achieved CR/CRh have been on study > 6 months and achieved negative MRD (minimal residual disease) status
- Consistent tumor burden reduction observed, 3 out of 5 patients with elevated blast counts achieving ≥ 50% reduction in blast counts

In patients with spliceosome-mutated R/R MDS, key findings included:

- Objective response rate of 57% (4 out of 7 patients)
- One of the patients who achieved a marrow CR (mCR) proceeded to stem cell transplant after 1 cycle
- Consistent tumor burden reduction observed, with 4 out of 7 patients achieving ≥ 50% reduction in blast counts

In patients with a FLT3 mutated R/R AML, key findings included:

- CR rate of 33% (1 out of 3 patients)
- 2 out of 3 patients showed eradication of FLT3 mutation following treatment, indicating potential to modify the disease
- Consistent tumor burden reduction observed; with 2 out of 3 patients with elevated blast counts achieving ≥ 50% reduction in blast counts

We believe the data suggest a favorable safety and anti-cancer activity profile compared to standard of care therapies for these patient populations.

Enrollment in the study of CA-4948 in R/R AML/MDS is on-going, and Curis looks forward to potential discussions with the FDA in the first half of 2022 regarding the potential for a rapid registrational path forward for CA-4948 as a monotherapy in genetically-defined patient populations. Curis expects to provide additional data from the R/R AML/MDS study at a medical meeting in 2022.

Phase 1 monotherapy study of CI-8993 in R/R solid tumors

Promising Safety Profile – No DLTs

Based on 13 patients treated in the first two dose cohorts of 0.15mg/kg and 0.3mg/kg, we believe CI-8993 has shown a promising safety profile to date, with no dose-limiting toxicities observed.

Following the implementation of safety measures including step dosing and co-medication, the trial has successfully dose escalated through the 0.15 mg/kg and 0.3 mg/kg cohorts, the dose level at which Janssen discontinued a prior study after a patient experienced a reversible grade 3 treatment-related adverse event.

The current study of CI-8993 in patients with solid tumors is currently enrolling at 0.6 mg/kg.

Encouraging PK/PD Activity

In the prior Janssen study, CI-8993 had demonstrated that, at low doses, a "sink effect" limited the amount of CI-8993 that could be detected in the circulation of patients. In the current Curis study, CI-8993 has shown non-linear increases in pharmacokinetic (PK) exposure at each dose level and exhibits saturation kinetics, indicating the potential to overcome this sink effect as we increase dose. These findings suggest the potential for broad bioavailability at higher dose levels. The pharmacodynamic (PD) effects of CI-8993 in patients observed to date suggest the possibility that CI-8993 can activate multiple anti-cancer immune mechanisms, including mechanisms that are not addressed by currently approved checkpoint inhibitors. Curis intends to further explore this PK/PD relationship at higher dose levels, as the study continues.

Curis expects to report expanded safety and tolerability data, along with initial PK, PD and anti-cancer data from the trial in the second half of 2022.

Conference Call Information

Curis management will host a conference call today,January 6, 2022, at 8:00 a.m. ET, to discuss these results with Dr.Daniel DeAngelo, Chief, Division of Leukemia at Dana-Farber Cancer Institute.

To access the live conference call, please dial 1-888-346-6389 fromthe United States or 1-412-317-5252 from other locations, shortly before 8:00 a.m. ET. The conference call can also be accessed on the Curis website atwww.curis.com in the Investors section.

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 mutation such as SF3B1 and U2AF1. In addition to inhibiting IRAK4, CA-4948 was also designed to inhibit FLT3, a known oncologic driver, which may provide additional benefit in patients with AML and MDS.

About CI-8993

CI-8993 is a monoclonal IgG1κ antibody with active Fc, designed to antagonize the V-domain Ig suppressor of T-cell activation (VISTA) signaling pathway. VISTA is a novel negative checkpoint ligand expressed on myeloid cells and T cells that is homologous to PD-1/PD-L1. VISTA enhances T cell quiescence and myeloid derived immune suppressor cells (MDSCs). CI-8993 relieves negative regulation by hematopoietic cells and enhances protective anti-tumor immunity. Preclinically, VISTA monoclonal antibody treatment increased the number of tumor-specific T cells in the periphery, and enhanced the infiltration, proliferation and effector function of tumor-reactive T cells within the tumor microenvironment (TME). VISTA blockade alters the suppressive feature of the TME by decreasing the presence of monocytic and granulocytic MDSCs and increasing the presence of activated dendritic cells (DCs) within the TME leading to enhanced T cell mediated immunity. VISTA monoclonal antibody administration as a monotherapy has been shown to suppress the growth of both transplantable and inducible melanoma in preclinical models. CI-8993 was originally developed as part of a license and collaboration agreement between ImmuNext and Janssen Biotech, Inc (Janssen). In 2016, Janssen initiated clinical development of CI-8993 in a Phase 1 study of CI-8993 in patients with advanced solid tumors. The study enrolled 12 patients, in which one patient experienced dose-limiting side effects related to cytokine release syndrome. Afterwards, Janssen opted to close the study and ImmuNext regained control of the asset. Curis is engaged in a collaboration with ImmuNext for the development of CI-8993.

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 trial 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'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 concerning expectations of the potential for Curis's proprietary drug candidates CA-4948 and CI-8993, including with respect to the potency, anti-cancer activity, durability and tolerability of CA-4948 and CI-8993; future studies with respect to CA-4948 and CI-8993; the potential advantages and benefits of CA-4948, CI-8993 and checkpoint inhibitors over other therapies; and Curis's plans to advance its development programs for CA-4948 and CI-8993, including with respect to anticipated results, clinical trials, regulatory and commercialization plans and timelines; 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, or the CRADA with National Cancer Institute, will continue for their full terms, , that Curis or its collaborators will each maintain the financial and other resources necessary to continue financing their respective portions of the research, development and commercialization costs, or that the parties will successfully discover, develop or commercialize

drug candidates under the collaborations. 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 Curis's most recent Form 10-K and Form 10-Q, and the factors that are discussed in other filings that Curis periodically makes 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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