Curis Announces Initiation of Investigator-Sponsored Phase 2 LUCAS Study of CA-4948 for the Treatment of Anemia in Patients with Very Low, Low, or Intermediate-Risk Myelodysplastic Syndromes

- Phase 2 study sponsored by investigators at Universität Leipzig in Germany -

LEXINGTON, Mass., Feb. 2, 2021 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today announced the initiation of a Phase 2 investigator-sponsored trial (IST) evaluating CA-4948, a novel, small molecule IRAK4 kinase inhibitor, for the treatment of anemia in patients with very low, low, or intermediate-risk myelodysplastic syndromes (MDS). The study is being led by Uwe Platzbecker, M.D., Ph.D., Professor and Director of the Medical Clinic and Polyclinic for Hematology, Cell Therapy, and Hemostaseology at the University Hospital in Leipzig. Dr. Platzbecker is co-founder and chairman of both the European Myelodysplastic Syndromes Cooperative Group (EMSCO) and the German MDS Study Group (D-MDS). Furthermore, he acts as co-chairman of the European Hematology Association's Scientific Working Group on MDS.

"Following the very promising preliminary data we presented in December in patients with relapsed/refractory AML and high-risk MDS, we are eager to further explore if CA-4948 may also provide benefit in other indications, including in MDS patients with lower risk profiles. To that end, we are excited to collaborate with Dr. Platzbecker, a renowned MDS clinician," said James Dentzer, President and Chief Executive Officer of Curis. "This IST, along with the previously announced CRADA with the NCI, will enable us to leverage the resources of large, highly regarded institutions as we continue to advance and broaden our IRAK4 clinical program."

"As we have learned through intensified surveillance strategies for asymptomatic lower-risk MDS, there is a distinct need for safe treatments to modify the natural history of early MDS before it progresses to AML. These patients often have higher genetic risk prognoses, worsening cytopenia, an increase in the number of circulating or bone marrow blasts, and signs of cytogenetic evolution," said Dr. Platzbecker, the lead investigator on the LUCAS study. "Current therapies that target anemia in genetically defined lower-risk MDS with erythropoiesis stimulating agents are effective, but transient, often ending in progression and disease complications. As a direct, non-myelosuppressive target of IRAK4, CA-4948 may possess safe disease-modifying potential in lower-risk MDS that can slow or prevent further progression."

About the Phase 2 LUCAS Trial

The LUCAS study is a Simon 2-stage Phase 2, open-label, multicenter trial evaluating the safety and efficacy of CA-4948 monotherapy for the treatment of anemia in patients with very low, low, or intermediate risk MDS. The trial is expected to start recruitment in the second quarter of 2021 at 17 sites of the D-MDS and is designed to enroll 84 patients across two cohorts consisting of 42 patients each. Cohort A will include erythropoiesis stimulating agent (ESA) refractory/intolerant patients and Cohort B will include ESA naïve patients with transfusion dependence (min. 20 patients) or transfusion independence (min. 20 patients).

Patients in both cohorts will receive 300mg CA-4948 twice-daily (BID) for 21 days in at least four repeating cycles lasting 28 days each. The primary endpoint of the study is to evaluate the proportion of patients that develop an erythroid response (HI-E) according to IWG 2018 criteria. Secondary and exploratory endpoints of the study include: broader anti-cancer activity, safety & toxicity, and predictive biomarkers. An interim analysis for futility will be conducted after 21 patients have completed the designated treatment period in either cohort.

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 trial in patients with non-Hodgkin's lymphoma and in a Phase 1 trial in patients with acute myeloid leukemia and myelodysplastic syndromes. 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 1a/1b 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.

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 any expectations of the potential for the Company's proprietary drug candidate CA-4948, including the potential developments and benefits of CA-4948 under the investigator-sponsored LUCAS study, and any statements with respect to the LUCAS study, the CRADA with NCI, and the Company's ability to advance and broaden its clinical programs. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "intends," "seeks," "estimates," "assumes," "will," "may," "could" 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, 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 also faces risks relating to 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 caption "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.

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