Curis Announces Collaboration with the National Cancer Institute for the Development of IRAK4 Inhibitor, CA-4948, as an Anti-Cancer Agent

LEXINGTON, Mass., Nov. 10, 2020 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today announced that it has entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute (NCI), a component of the National Institutes of Health, for joint development of CA-4948, a first-in-class small molecule IRAK4 kinase inhibitor, as an anti-cancer agent under the NCI Experimental Therapeutics Program (NExT).

Under the CRADA, Curis will collaborate with the NCI Cancer Therapy Evaluation Program to conduct non-clinical and clinical studies of Curis's proprietary compound CA-4948, an IRAK-4 kinase inhibitor that acts as a Toll-like Receptor (TLR) suppressor, as an anti-cancer agent.

"In addition to expanding the reach of this important clinical program, we believe this CRADA will provide powerful validation of our target-specific approach to developing impactful novel therapeutics for patients suffering from devastating cancers," said James Dentzer, President and Chief Executive Officer of Curis. We look forward to working closely alongside the team at the NCI and utilizing their tremendous expertise and resources as we advance CA-4948 through the clinical process."

About CA-4948

CA-4948 is a small molecule inhibitor of IRAK4, which is currently being tested in a Phase 1 dose escalating clinical trial in patients with non-Hodgkin lymphomas, including those with Myeloid Differentiation Primary Response 88 ("MYD88"), alterations. CA-4948 is also being investigated in a separate Phase 1 trial for acute myeloid leukemia and myelodysplastic syndromes. The Company is planning a combination study of CA-4948 and ibrutinib, a BTK inhibitor, in non-Hodgkin lymphomas with planned enrollment commencing in the fourth quarter of 2020.

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 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's 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 the potential developments and benefits of CA-4948 under the CRADA, the Company's plans to work with the NCI to advance CA-4948, and the Company's expectations regarding NCI's expertise and resources, and the validation of the Company's target-specific approach to developing impactful novel therapeutics. 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. 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 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. If it is unable to continue as a going concern, it may have to liquidate its assets and may receive less than the value at which those assets are carried on its audited financial statements, and it is likely that investors will lose all or a part of their investment. 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 Curis's ongoing or planned 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. 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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