Curis Announces FDA Clearance of IND Application for CI-8993, the First-In-Class Monoclonal Anti-VISTA Antibody

- Phase 1a/1b dose escalation study to begin in the second half of 2020 -

LEXINGTON, Mass., June 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 the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for CI-8993, the first-in-class monoclonal anti-VISTA antibody. Curis plans to initiate a Phase 1a/1b study of CI-8993 in the second half of 2020.

"The clearance of our IND is an important step for the advancement of VISTA therapies, as CI-8993 becomes the first anti-VISTA antibody in development to enter clinical testing," said James Dentzer, President and Chief Executive Officer of Curis. "When activated, VISTA plays a critical role in suppressing T cell activity. Conversely, it has been shown in preclinical studies that blocking VISTA reduces the suppression of T cells and reactivates anti-tumor immune function. We are eager to leverage our extensive experience with VISTA and pioneer this first-in-class anti-VISTA antibody program."

Certain cancers, such as mesothelioma, triple negative breast cancer, non-small cell lung cancer, and gynecologic malignancies, are known to be highly driven by VISTA. These cancers may be amenable to monotherapy treatment with anti-VISTA therapy.

In other cancers, anti-VISTA therapy may be more effective as part of a combination approach. VISTA is independent of, and complementary to, other immune checkpoints, including PD1 and CTLA4. Published studies have shown that VISTA expression increases up to 5-fold as a compensatory mechanism following anti-CTLA4 or anti-PD1 treatment. Further preclinical studies have explored this relationship more deeply and support the potential of combining anti-VISTA therapy with anti-PD1 or anti-CTLA4 therapies.

The multi-center, open-label Phase 1a/1b dose escalation study of CI-8993 in patients with relapsed / refractory solid tumors will evaluate approximately 50 patients, with the goal of identifying a recommended dose and schedule. Curis expects to initiate this study in the second half of 2020.

About VISTA

VISTA is a novel negative checkpoint ligand that is homologous to PD-1/PD-L1 and suppresses T cell activation. VISTA relieves negative regulation by hematopoietic cells and enhances protective anti-tumor immunity, and is highly expressed on myeloid cells and T cells. 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 myeloid-derived suppressor cells 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. Previous studies have demonstrated that VISTA blockade may be synergistic with peptide-based cancer vaccines to impair the growth of established tumors.

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. In addition, Curis is engaged in a collaboration with ImmuNext for development of CI-8993, a monoclonal anti-VISTA antibody. 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 CI-8993, including with respect to the potential activity, safety and tolerability of CI-8993 and

future studies with respect to CI-8993, the potential advantages and benefits of CI-8993 to reduce the suppression of T cells and reactivate anti-tumor immune function, optimization of CI-8993, the Company's plans to initiate a Phase 1a/1b trial of CI-8993 in the second half of 2020, and the Company's expectations regarding the potential therapeutic benefit of CI-8993. 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.

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