Curis Announces Option and License Agreement with ImmuNext for the Development and Commercialization of Anti-VISTA Antibodies

- Curis to initiate Phase 1a/1b study for CI-8993 in 2020 -

LEXINGTON, Mass., Jan. 7, 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 an option and license agreement to acquire exclusive, worldwide rights from ImmuNext Inc. (ImmuNext) to develop and commercialize anti-VISTA antibodies for the treatment of cancer, including ImmuNext's lead compound, CI-8993 (formerly JNJ-61610588). CI-8993 is a clinical-stage monoclonal antibody designed to antagonize the V-domain Ig suppressor of T cell activation (VISTA) signaling pathway.

"This agreement aligns with our mission to develop the next generation of targeted cancer therapies and extends our leadership in developing anti-VISTA therapeutics," said James Dentzer, President and Chief Executive Officer of Curis. "The ImmuNext team and Dr. Randolph Noelle, whose lab in the Geisel School of Medicine at Dartmouth College co-developed the original characterization of VISTA biology, bring world-class expertise that will be invaluable to our collaboration as we seek to optimize the clinical development of CI-8993."

"VISTA is an important negative checkpoint regulator that plays a key role in the immune suppression induced by cancer," said Dr. Robert Martell, Head of R&D at Curis. "Recent studies also suggest VISTA is strongly upregulated in response to treatment with other cancer immunotherapy agents. We believe, a therapeutic antibody that can target and suppress VISTA represents a compelling single-agent strategy to potentially reverse tumor immune suppression and prevent resistance to other checkpoint inhibitors. In 2019, Curis led the clinical development of the first anti-VISTA program with a small molecule, CA-170. We look forward to leveraging that experience in 2020, this time with an antibody."

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 evaluating safety, pharmacokinetics and pharmacodynamics of ascending doses 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. Janssen opted to close the study and ImmuNext regained control of the asset.

"In the years since the original CI-8993 study, the advent of CAR-T therapy and broad expansion of immunotherapy have led to an evolution within the oncology community toward the safe management of "on-target" side effects such as cytokine release and immune-mediated toxicity. For example, in 2018, the National Comprehensive Cancer Network (NCCN) developed its Guidelines for Management of Immunotherapy-Related Toxicities. We believe the time is right to re-introduce CI-8993 into the clinic as a potentially transformative new therapy for patients," said Dr. Martell.

Under the terms of the agreement with ImmuNext, Curis will make an upfront payment to ImmuNext in exchange for an option to obtain an exclusive, worldwide license to develop and commercialize ImmuNext's anti-VISTA compounds and products containing these compounds in the field of oncology. This option is exercisable upon the earlier of: (i) four years from signing of the agreement; and (ii) 90 days after database lock for the first Phase 1a/1b trial in which the clinical endpoints are satisfied. Upon option exercise, Curis will pay ImmuNext an option exercise fee. ImmuNext is also eligible to receive future potential development, regulatory, and commercial milestone payments, as well as royalties on product sales.

For more information regarding the financial and other terms of the agreement, please refer to the Current Report on Form 8-K filed by Curis with the U.S. Securities & Exchange Commission on January 7, 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.

Clinically, VISTA is strongly expressed in several tumor types including pancreatic cancer, mesothelioma, and prostate cancer. VISTA creates an immune blocking signal that is independent of, and complementary to, PD-1 and CTLA-4. VISTA expression in patient samples increases as a compensatory reaction to treatment with PD-1 and CTLA-4 directed therapy.

About Curis, Inc.

Curis is a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, including fimepinostat, which is being investigated in combination with venetoclax in a Phase 1 clinical study in patients with DLBCL. Curis is also engaged in 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 November 2019, Curis announced that no further patients will be enrolled in its Phase 1 study of CA-170, an orally available, dual inhibitor of VISTA and PDL1, in malignant plural mesothelioma patients (high VISTA expressors), based on initial efficacy data. CA-170 was generally safe and well-tolerated in the study. The Company continues to evaluate the translational science and clinical pharmacodynamics of CA-170, in addition to patient data from the study, to assess potential opportunities for further evaluation of CA-170. 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 safe harbor provisions 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 reverse tumor immune suppression and prevent resistance to other checkpoint inhibitors, optimization of CI-8993 and Curis's plans to exercise the option under the option and license agreement with ImmuNext, potential payments by Curis under the agreement with ImmuNext and Curis's plans to develop CI-8993 and advance other development programs. Forward-looking statements may contain the words "believes," "expects," "anticipates," "plans," "seeks," "estimates," "assumes," "will," "may," "could," "predict," "project," "target," or the negative of these terms or other similar expressions. These forward-looking statements include, among others, statements about Curis's business, plans, prospects and strategies and its expectations regarding its option and license agreement with ImmuNext, including with respect to conducting a Phase 1a/1b trial. 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 faces a number of risks inherent in the research, development or commercialization of novel drugs to treat cancer and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. There can be no guarantee that the ImmuNext option and license agreement will continue for its full term, that Curis or ImmuNext will maintain the financial resources necessary to continue financing their respective portions of any research, development or commercialization costs. Curis will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. Without sufficient additional funding, Curis will not be able to continue as a going concern and may be forced to delay, reduce in scope or eliminate some of its research and development programs, which could adversely affect its business prospects and its ability to continue operations. Substantial doubt about Curis's ability to continue as a going concern may adversely affect Curis's ability to access the substantial additional capital needed to continue operations. Curis faces substantial competition. Curis's expectations with respect to the option and license agreement with ImmuNext and CI-8993 could also be affected by risks and uncertainties relating to a failure of Curis or ImmuNext to fully perform under the option and license agreement and/or any early termination of the option and license agreement, adverse results of any clinical trials and non-clinical studies that are the subject of the collaboration, including subsequent analysis of both existing data and new data, the content and timing of decisions made by the U.S. Food & Drug Administration and other regulatory authorities, investigational review boards at clinical trial sites, and publication review bodies, and Curis's inability to enroll patients in clinical trials that may be initiated under the collaboration. 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 and unplanned expenses may adversely affect Curis's financial condition and its ability to access the substantial additional capital needed to fund the growth of its business. Important factors that may cause or contribute to such differences include the factors set forth under the caption "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.

SOURCE Curis, Inc.

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