Curis and Aurigene Announce Amendment of Collaboration for the Development and Commercialization of CA-170

- Aurigene to fund and conduct a Phase 2b/3 randomized study of CA-170 in patients with non-squamous non-small cell lung cancer (nsNSCLC) -
- Aurigene to receive Asia rights for CA-170; Curis entitled to royalty payments in Asia -

LEXINGTON, Mass., Feb. 6, 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 amendment of its collaboration, license and option agreement with Aurigene Discovery Technologies, Ltd. (Aurigene). Under the terms of the amended agreement, Aurigene will fund and conduct a Phase 2b/3 randomized study evaluating CA-170, an orally available, dual inhibitor of VISTA and PDL1, in combination with chemoradiation, in approximately 240 patients with non-squamous non-small cell lung cancer (nsNSCLC). In turn, Aurigene receives rights to develop and commercialize CA-170 in Asia, in addition to its existing rights in India and Russia, based on the terms of the original agreement. Curis retains U.S., E.U., and rest of world rights to CA-170, and is entitled to receive royalty payments on potential future sales of CA-170 in Asia.

In 2019, Aurigene presented clinical data from a Phase 2a basket study of CA-170 in patients with multiple tumor types, including those with nsNSCLC. In the study, CA-170 demonstrated promising signs of safety and efficacy in nsNSCLC patients compared to various anti-PD-1/PD-L1 antibodies.

"We are pleased to announce this amendment which leverages our partner Aurigene's expertise and resources to support the clinical advancement of CA-170, as well as maintain our rights to CA-170 outside of Asia," said James Dentzer, President and Chief Executive Officer of Curis. "Phase 2a data presented at the European Society for Medical Oncology (ESMO) conference last fall supported the potential for CA-170 to serve as a therapeutic option for patients with nsNSCLC. We look forward to working with our partner Aurigene to further explore this opportunity."

"Despite recent advancements, patients with localized unresectable NSCLC struggle with high rates of recurrence and need for expensive intravenous biologics. The CA-170 data presented at ESMO 2019 from Aurigene's Phase 2 ASIAD trial showed encouraging results in Clinical Benefit Rate and Prolonged PFS and support its potential to provide clinically meaningful benefit to Stage III and IVa nsNSCLC patients, in combination with chemoradiation and as oral maintenance" said Kumar Prabhash, MD, Professor of Medical Oncology at Tata Memorial Hospital, Mumbai, India.

Murali Ramachandra, PhD, Chief Executive Officer of Aurigene, commented, "Development of CA-170, with its unique dual inhibition of PD-L1 and VISTA, is the result of years of hard-work and commitment by many people, including the patients who participated in the trials, caregivers and physicians, along with the talented teams at Aurigene and Curis. We look forward to further developing CA-170 in nsNSCLC."

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. 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.

About Aurigene

Aurigene is a development stage biotech company engaged in discovery and clinical development of novel and best-in-class therapies to treat cancer and inflammatory diseases and a wholly owned subsidiary of Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY). Aurigene is focused on precision- oncology, oral immune checkpoint inhibitors, and the Th-17 pathway. Aurigene currently has several programs from its pipeline in clinical development. Aurigene's ROR-gamma inverse agonist AUR-101 is currently in phase 2 clinical development under a US FDA IND. Additionally, Aurigene has multiple compounds at different stages of pre-clinical development. Aurigene has partnered with many large and mid-pharma companies in the United States and Europe and has 15 programs currently in clinical development. For more information, please visit

Aurigene's website at http://aurigene.com/.

Forward-Looking Statements

Any statements in this press release including, without limitation, statements regarding any expectations of the potential for CA-170, including with respect to the potential activity, safety and tolerability of CA-170 and future studies with respect to CA-170 including any studies conducted or to be conducted by Aurigene constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. 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 collaboration, license and option agreement with Aurigene, as amended, including the second amendment (as described below). 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 Aurigene collaboration, license and option agreement, amended, or the second amendment, will continue for its full term or that Curis or Aurigene 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 collaboration, license and option agreement, the second amendment and CA-170 could also be affected by risks and uncertainties relating to a failure of Curis or Aurigene to fully perform under the collaboration, option and license agreement or the second amendment and/or any early termination of such agreement or amendment, adverse results of any clinical trials and non-clinical studies that are the subject of the collaboration, including subsequent analysis of existing data and new data received from future studies, 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 or Aurigene'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 as of the date of this press release 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.

For further information: Curis Investor Relations, Jane Urheim, Stern Investor Relations, Inc., (212) 362-1200, jane.urheim@sternir.com; Aurigene Media Contact, Subir Dubey, Business Development, +91 80 7102 5571, subir_d@aurigene.com

---

Additional assets available online: Photos (1)

http://investors.curis.com/2020-02-06-Curis-and-Aurigene-Announce-Amendment-of-Collaboration-for-the-Development-and-Commercialization-of-CA-170