Curis Announces Positive Safety, Tolerability and Pharmacokinetic Data in Ongoing Phase 1 Study of Fimepinostat in Combination with Venetoclax

- 11 patients enrolled to-date in Phase 1 study; combination has been generally well-tolerated -
- No drug-drug pharmacokinetic (PK) interaction that required dose modification of either agent -
- Fimepinostat poster to be presented at 61st Annual Meeting of the American Society of Hematology (ASH) -
- Management to host conference call today at 8:00 a.m. ET -

LEXINGTON, Mass., Dec. 6, 2019 /PRNewswire/ -- Curis, Inc. (NASDAQ: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, today announced preliminary tolerability and PK data from its ongoing Phase 1 dose-finding study of fimepinostat, a small molecule dual inhibitor of PI3K/HDAC and suppressor of MYC, in combination with venetoclax, a BCL-2 inhibitor, for the treatment of patients with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL), including patients with double-hit/double-expressor (DH/DE) lymphoma.

"We are very pleased with the progress in our ongoing Phase 1 study, with the combination of fimepinostat and venetoclax demonstrating a favorable tolerability profile thus far," said James Dentzer, President and Chief Executive Officer of Curis. "We believe demonstrating that this combination is generally well-tolerated for patients is a significant milestone, as both drugs have shown activity as monotherapies in this patient population and we believe activity will be improved by combining the two agents. Based on these data, we plan to initiate an expansion of the current study in 2020."

To date, the study has enrolled 11 patients, 6 patients in the first cohort and 5 patients in the second cohort. Patients in the first cohort received 30mg once-daily (QD) of fimepinostat and 400mg QD of venetoclax, while the patients in the second cohort received 60mg QD of fimepinostat and 400mg QD of venetoclax. To date the combination has been generally well-tolerated by patients.

"There is an urgent need for therapies targeting MYC and BCL-2 alterations, particularly in DH/DE lymphoma, a disease defined by these alterations and one of the deadliest types of lymphoma," said Robert Martell, M.D, Ph.D, Head of R&D at Curis. "We believe fimepinostat is unique in its ability to target MYC through simultaneous inhibition of both PI3K and HDAC. Venetoclax is a rapidly-acting inhibitor of BCL2, the other key abnormality in DH lymphoma. Supported by synergistic anti-cancer effects observed in preclinical models, we believe this is an ideal combination to target DLBCL and we look forward to gaining further insights on the combination from this study.

Dr. Martell continued: "The study was designed with initial patients undergoing a several-week run-in period allowing detailed PK interaction analysis and venetoclax ramp-up to be performed. In preliminary analyses, we found the combination to be generally well tolerated, with no dose-limiting toxicity (DLT) in the first cohort and one DLT of transient grade 3 diarrhea in the second cohort. Importantly, we found no drug-drug PK interaction that required dose modification of either agent. Drug-drug interactions are a major problem for many drugs combining with venetoclax, and we are encouraged that we have not seen such interaction to date with fimepinostat."

Curis' ongoing Phase 1, open-label, multi-center, dose-finding 3+3 study is designed to evaluate the safety and tolerability, PK and pharmacodynamics, and preliminary activity of the fimepinostat and venetoclax combination in patients with DLBCL, including those with DH/DE lymphoma. Patients are enrolled in two cohorts in the study, with fimepinostat administered on a 5-days-on-2-days-off schedule in combination with venetoclax in 21-day cycles. Curis plans to initiate an expansion of the current study in 2020.

Conference Call Information

Curis management will host a conference call today, December 6, 2019, at 8:00 a.m. ET, to discuss these results. To access the live conference call, please dial 1-888-346-6389 from the United States or 1-412-317-5252 from other locations, shortly before 8:00 a.m. ET. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

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 clinical studies in patients with DLBCL and solid tumors. 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. 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 fimepinostat, including with respect to the activity, safety and tolerability of fimepinostat and expansion of the current study with respect to fimepinostat, the potential advantages and benefits of small molecule checkpoint antagonists, and the Company's plans to advance its development programs, including the Company's plans for fimepinostat. 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, including without limitation fimepinostat, may not be replicated in later trials. There can be no guarantee that the collaboration agreement with Aurigene will continue for its full term, that Curis or Aurigene 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. 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 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 and unplanned expenses may adversely affect Curis's financial conditions 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 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. 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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