Curis Provides First-Ever Demonstration that Targeting IRAK4 in Patients with Relapsed/Refractory Non-Hodgkin's Lymphoma Results in Anti-Cancer Activity in Ongoing Phase 1 Study

- Preliminary clinical data on CA-4948 demonstrates anti-cancer activity and favorable safety profile -
- Establishes proof of concept that targeting IRAK4 may be a viable anti-cancer strategy -
- Curis to continue dose escalation in ongoing Phase 1 study and plans to launch two additional clinical studies with CA-4948 -
- 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 updated preliminary data from its ongoing Phase 1 dose escalation study of CA-4948, an IRAK4 kinase inhibitor, for the treatment of patients with relapsed or refractory (R/R) non-Hodgkin's lymphoma (NHL), including patients with diffuse large B-cell lymphoma (DLBCL), Waldenström's macroglobulinemia (WM) and oncogenic MYD88 mutations.

"We are very encouraged by the anti-cancer activity that we have observed to date from CA-4948 during dose escalation in our Phase 1 study," said Robert Martell, MD, PhD, Head of R&D at Curis. "Notably, five of the six patients evaluable for anti-cancer activity at the two highest dose levels of CA-4948 have experienced reduced tumor burden. Additionally, treatment for three of these five patients is ongoing after 33 to 51 weeks. These findings illustrate dose dependent activity compared to earlier dose levels."

Dr. Martell continued: "We believe these results achieve the desired activity outcome for a targeted single agent treating malignancies with complex molecular genetics. Unlike the minority of cancers with a single driver mutation, these genetically complex malignancies have aberrant signaling through multiple signaling pathways. One such pathway is the oncogenic TLR pathway, which depends on IRAK4. Such complex cancers represent the bulk of actual medical need in oncology today, and we believe the most effective therapeutic approaches in these situations is to target multiple such mechanisms. Indeed, synergy was observed preclinically when combining CA-4948 with either BTK inhibitors or a BCL2 inhibitor, and we intend to explore combinations in the clinic."

"We believe these updated clinical data further support the potential of CA-4948 to become a safe, effective therapeutic option for patients with NHL," said James Dentzer, President and Chief Executive Officer of Curis. "CA-4948 is currently the most advanced molecule targeting IRAK4 in clinical development for cancer and given these exciting results, we intend to move aggressively to advance CA-4948 with the goal of bringing this promising new therapy to patients in need. We look forward to expanding the development of CA-4948 with two new clinical trials in 2020 that will study CA-4948 in AML/MDS and in combination therapy in NHL."

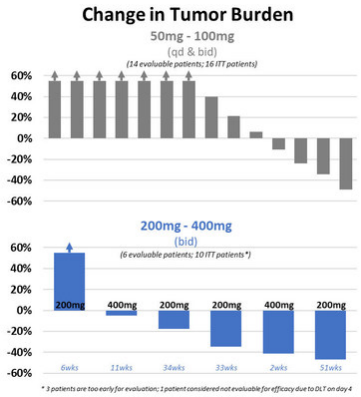
The reported data are from Curis's ongoing Phase 1, open-label, dose escalation 3+3 study designed to evaluate the safety and tolerability of CA-4948, in addition to pharmacokinetics, pharmacodynamics, and anti-cancer activity, in patients with R/R NHL. Patients have been treated in continuous 21-day cycles and at dose levels of 50mg once-daily (QD), 50mg twice-daily (BID), 100mg QD, 100mg BID, 200mg BID and 400mg BID.

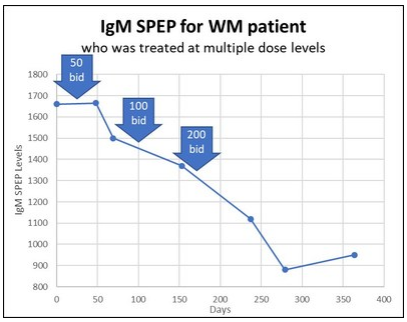
Key findings include:

- CA-4948 was demonstrated to be generally well-tolerated.
- Patients enrolled to date include patients with tumor types of DLBCL, WM, marginal zone lymphoma, follicular lymphoma, and lymphoplasmacytic lymphoma.
- Anti-cancer activity, as measured by the reduction of tumor burden, was observed in:
  - 5 out of 6 evaluable patients in the highest dose cohorts of 200mg BID and 400mg BID, with a mean reduction of 29% (ranging from 5% to 47%).
  - One patient with WM, who dose escalated from 50mg BID to 100mg BID, and then to 200mg BID, experienced dose-corresponding reductions in tumor burden. This patient remains on therapy.
  - One patient with DLBCL enrolled in the 200mg dose cohort remains on study and has seen tumor reductions of 35%.
- One patient treated at 100mg QD had a dose-limiting toxicity (DLT) of maculo-papular rash, which was resolved after steroid treatment. Another patient treated at 400mg BID experienced a DLT of Grade 3 rhabdomyolysis.

Curis is currently evaluating patients at the 400mg BID dose of CA-4948 in its Phase 1 study and plans to

continue dose escalation until the maximum tolerated dose and or recommended Phase 2 dose of CA-4948 is determined.





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 CA-4948, including with respect to the activity, safety and tolerability of CA-4948 and future studies with respect to CA-4948, the potential advantages and benefits of small molecule checkpoint antagonists, and the Company's plans to advance its development programs. 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 CA-4948, 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.

SOURCE Curis, Inc.

For further information: Investor Relations, Jane Urheim, Stern Investor Relations, Inc., (212) 362-1200, jane.urheim@sternir.com

---