Curis Announces Advancement to the 200mg BID Cohort in the CA-4948 Study

LEXINGTON, Mass., April 8, 2019 /PRNewswire/ -- Curis, Inc. (Nasdaq: CRIS), a biotechnology company focused on the development of innovative therapeutics for the treatment of cancer, announced today that it has begun dosing patients in the 5th cohort (200mg BID; total daily dose of 400mg) in the Phase 1 trial of CA-4948, an orally available small molecule inhibitor of IRAK4, for treatment of patients with non-Hodgkin lymphoma, including those with MYD88 alterations.

"This is an important milestone in the execution of our clinical program," said James Dentzer, the Company's President and Chief Executive Officer. "Last fall, we re-organized the company to heighten focus on clinical execution and laid out an aggressive goal to advance to the 5th cohort (200mg BID) in time for a midyear 2019 release of initial data. We are pleased to announce that we have begun dosing the 5th cohort sooner than expected and we re-iterate our plan to report initial clinical data this summer."

About CA-4948, a Small-Molecule Inhibitor of IRAK4

Innate immune responses orchestrated through Toll-like receptors or certain interleukin receptors are important mediators of the body's initial defense against foreign antigens, while their dysregulation is associated with certain inflammatory conditions. Toll-like receptor and interleukin receptor signaling through the adaptor protein MYD88, results in the assembly and activation of IRAK4, initiating a signaling cascade that induces cytokine and survival factor expression mediated by the transcription factor NFκB. More recently, components of this pathway are recognized to be genetically altered and have important roles in specific human cancers. MYD88 gene mutations are shown to occur in approximately 30% of Activated B-Cell (ABC) subtype of diffuse large B-cell lymphomas (DLBCL)[1,2] and in over 90% of the B-cell malignancy Waldenstrom's macroglobulinemia.[3] Due to IRAK4's central role in these signaling pathways, it is considered an attractive target for generation of therapeutics to treat these B-cell malignancies as well as certain inflammatory diseases.

[1] Nature. 2011; 470(7332):115–119

[2] Immunology and Cell Biology. 2011; 89(6):659–660

[3] N Engl J Med. 30, 2012; 367(9):826–833

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 to develop first-in-class therapeutics in 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-170 is currently undergoing testing in a Phase 1 trial in patients with advanced solid tumors, lymphomas, and mesothelioma and in a Phase 2 trial in India conducted by Aurigene. 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.

SOURCE Curis, Inc.

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