

Curis Announces GDC-0449 Phase II Ovarian Cancer Trial Design

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 28, 2008--Curis, Inc. (NASDAQ: CRIS), a drug development company focused on developing the next generation of proprietary targeted medicines for cancer treatment, today announced that its collaborator Genentech, Inc. has indicated that it expects to initiate a Phase II clinical trial of GDC-0449, an orally-administered small molecule Hedgehog antagonist, as a maintenance therapy for ovarian cancer patients in second or third complete remission. Genentech is developing GDC-0449 under a collaboration agreement with Curis and will be the sponsor of this study.

GDC-0449 will be evaluated in approximately 100 patients with ovarian cancer in second or third complete remission in a randomized, placebo-controlled, double-blind, multi-center Phase II trial. Patients will be randomized in a 1:1 ratio to receive either GDC-0449 or a placebo comparator and will be stratified based on whether their cancer is in a second or third complete remission. The primary endpoint of the trial is progression-free survival, and secondary outcome measures include overall survival, the amount of Hedgehog protein expression in archival tissue and tracking of adverse events. Genentech has indicated that it expects to initiate this Phase II trial during the second half of 2008. Trial details are posted at ClinicalTrials.gov.

"We believe that the dysregulation of developmental pathways such as Hedgehog may play a role in the formation or recurrence of cancer. Therefore, we are hopeful that a Hedgehog inhibitor, such as GDC-0449, may be a useful therapeutic tool in preventing cancer from returning in these ovarian cancer patients and may prove useful as a maintenance therapy," said Curis President and CEO Dan Passeri. "GDC-0449 is currently in Phase II testing in first-line metastatic colorectal cancer and Genentech has indicated that it expects to initiate an additional Phase II clinical trial in advanced basal cell carcinoma in the second half of 2008."

About Curis, Inc.

Curis is a drug development company that is committed to leveraging its innovative signaling pathway drug technologies to seek to create new medicines, primarily for cancer. In expanding its drug development efforts in the field of cancer through its targeted cancer drug development platform, Curis is building upon its previous experiences in targeting signaling pathways for the development of next generation targeted cancer therapies. For more information, visit Curis' website at www.curis.com.

Cautionary Statement: This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation statements regarding Genentech's plans to initiate three Phase II clinical trials of GDC-0449 and the Company's expectations regarding the potential clinical benefits of GDC-0449 in advanced ovarian cancer. The Company may use words such as "believes", "expects", "anticipates", "plans", "seeks", "estimates", "will", "may" or similar expressions to identify these forward-looking statements. There are important factors that may cause actual results to be materially different from those indicated by such forward-looking statements including, among other things, risks relating to: the potential for adverse results, delays and/or failures in the Company's targeted cancer drug development program, including without limitation unplanned delays and/or failures in its clinical trial of CUDC-101 and its ongoing preclinical studies of CUDC-305; the success of the Company's collaboration with Genentech, including the risks that Genentech may experience adverse results, delays and/or failures in the Hedgehog pathway antagonist program currently under clinical development and that the Company may have no control over, or foreknowledge of, the progress of this program; difficulties or delays in obtaining or maintaining required regulatory approvals for products under development both internally and through the Genentech collaboration; the Company's ability to obtain or maintain necessary intellectual property protection; adverse changes in the Company's ability to successfully execute its business plan, including the Company's ability to obtain the substantial additional funding required for such execution; unplanned cash requirements and expenditures which, among other things, could shorten the estimated period in which the Company will have cash to fund its operations and which could also adversely affect the Company's estimated operating expenses for 2008 and beyond; risks relating to the Company's ability to enter into and maintain planned collaborations and maintain its current collaborations with Genentech; and competitive pressures. The Company also faces other risk factors identified in the Quarterly Report on Form 10-Q for the quarter ended June 30, 2008 and other filings that it periodically makes with the Securities and Exchange Commission.

In addition, any forward-looking statements represent the Company's views only as of today and should not be relied upon as representing the 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.

CONTACT: Curis, Inc.
Michael P. Gray, 617-503-6632
Chief Financial Officer
mgray@curis.com

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