Curis Announces Nature Publication Elucidating a Paracrine Mechanism of Action in Hedgehog-Expressing Tumors

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 27, 2008--Curis, Inc. (NASDAQ: CRIS), a drug development company focused on developing next generation proprietary targeted medicines for cancer treatment, today announced the publication of preclinical data in Nature that support the premise that Hedgehog proteins play an important role in supporting tumor growth in Hedgehog-expressing solid tumors through a paracrine mechanism of action.

The paper reported that analysis of human tissue samples by Genentech scientists revealed that subsets of colorectal, endometrial, ovarian and pancreatic cancers overexpressed Hedgehog protein. The paper also included data on preclinical pancreatic and colon cancer xenograft models demonstrating that administration of a Hedgehog antagonist results in significant growth delay of the underlying tumor.

"This paper reports compelling evidence of paracrine signaling and the tumor growth inhibitory effects of Hedgehog antagonists. These data suggest that Hedgehog antagonists may have therapeutic value not just in cancers driven by mutations in the Hedgehog signaling pathway, such as basal cell carcinomas (BCC), but also potentially in cancers where Hedgehog signaling is driven by overexpression of the Hedgehog protein," said Dan Passeri, Curis' President and CEO. "We are encouraged by our collaborator Genentech's decision to conduct Phase II trials of GDC-0449 in colorectal and ovarian cancer, in addition to a study in metastatic and locally advanced BCC. We believe that the insights provided by these studies into the underlying mechanisms of Hedgehog's involvement in cancer may lead to more effective treatment regimens using Hedgehog antagonists such as GDC-0449."

In the paracrine setting, the Hedgehog protein is expressed by the tumor cells but has its biologic effect upon the surrounding supporting cells (stromal cells), including effecting these surrounding cells to support growth of the Hedgehog-secreting tumor cells. Genentech is currently conducting clinical testing of GDC-0449. In May 2008, Genentech initiated a Phase II clinical trial in which approximately 150 patients with colorectal cancer will be treated with chemotherapy in combination with bevacizumab and will be randomized to receive GDC-0449 or placebo. In addition, Genentech has indicated that it expects to initiate Phase II testing of GDC-0449 in advanced ovarian cancer during the second half of 2008.

Phase I investigators have presented encouraging efficacy and safety data on the treatment of advanced basal cell carcinoma patients with GDC-0449 during the American Association for Cancer Research (AACR) Annual Meeting in April 2008 (Abstract #LB-138) and the American Society of Clinical Oncology (ASCO) Annual Meeting in June 2008 (Abstract #3516). The data presented at AACR included the achievement of clinical benefit (clinical or radiological responses or prolonged stable disease) in 8 of 9 patients treated with GDC-0449. No dose-limiting adverse events occurred. Two cases of reversible drug-related Grade 3 hyponatremia (lowered serum sodium level) and one case of reversible Grade 3 drug-related fatigue were the only grade 3 events reported as of the data cutoff date of April 1, 2008. Genentech has indicated that it expects to initiate a Phase II advanced basal cell carcinoma clinical trial during 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 targeted small molecule drug candidates 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 the potential therapeutic benefits of drugs that are based upon Hedgehog antagonists; the expected benefits of insights provided by Hedgehog studies described in Nature , and Genentech's stated timelines for the planned development of drug candidates under the parties' Hedgehog antagonist collaboration. 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.

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