Curis Announces Genentech's Initiation of Hedgehog Antagonist Phase II Clinical Trial In Metastatic Colorectal Cancer

Trial tests oral administration of GDC-0449 in combination with bevacizumab and a standard chemotherapy regimen

CAMBRIDGE, Mass., May 05, 2008 (BUSINESS WIRE) -- 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 has initiated a Phase II clinical trial of GDC-0449, an orally-administered small molecule Hedgehog antagonist, in metastatic colorectal cancer. As a result, Genentech will make a $3 million cash payment to Curis under the companies' June 2003 collaboration agreement.

"We are hopeful that GDC-0449 may one day provide an additional option to the existing standard of care for metastatic colorectal cancer patients," said Curis President and CEO Dan Passeri. "In addition, Genentech previously has announced that it plans to initiate two additional Phase II clinical trials of GDC-0449 in the second half of 2008, including trials in advanced basal cell carcinoma, where patient responses have been observed in the ongoing Phase I study, and in an undisclosed advanced solid tumor of epithelial origin. We look forward to providing further updates on these programs in the future."

GDC-0449 will be evaluated in approximately 150 patients with metastatic colorectal cancer in combination with the current standard of care in a randomized, placebo-controlled, double-blind Phase II trial. Patients will receive either FOLFOX or FOLFIRI chemotherapy in combination with bevacizumab and will be randomized to receive GDC-0449 or placebo. They will be stratified based on the chemotherapy regimen chosen and whether or not Response Evaluation Criteria in Solid Tumors (RECIST) measurable disease is present at baseline. RECIST provides standard parameters to be used when documenting patient response for solid tumors. The primary objective of the trial is progression-free survival from randomization to disease progression or death. Secondary outcome measures include the measurement of Hedgehog protein expression in archival tissue and tracking of adverse events. Trial details are posted at ClinicalTrials.gov.

Colorectal cancer remains a major unmet medical need, with the American Cancer Society estimating that approximately 150,000 new cases and 50,000 deaths will be attributable to this cancer in the United States in 2008. Colorectal cancer is the second leading cause of cancer death in the United States and the third most frequently diagnosed cancer.

Should GDC-0449 advance into subsequent stages of clinical testing and regulatory approval, Curis would be eligible to receive additional cash milestone payments from Genentech. In addition, in the event the drug candidate is successfully commercialized, Curis would be eligible to receive royalties on product sales.

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. Forward-looking statements used in this press release may contain the words "believes", "expects", "anticipates", "plans", "seeks", "estimates", "will", "may" 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 including, among other things:

-- adverse results, delays and/or failures in the Company's internal product development programs, including without limitation unplanned delays and/or failures in the Company's efforts to file an investigative new drug application and further advance its product candidate, CUDC-101, and the other programs under its targeted cancer drug development platform;

-- adverse results, delays and/or failures in the Hedgehog pathway antagonist program currently under clinical development by the Company's collaborator, Genentech, for which the Company may have no foreknowledge and over which the Company will have no control;

-- difficulties or delays in obtaining or maintaining required regulatory approvals for products being developed by the Company internally and through its collaboration with Genentech;

-- Curis' ability to obtain or maintain the patent and other proprietary intellectual property protection necessary for the development and commercialization of products based on its technologies;

-- changes in, or Curis' inability to execute, its business plan;

-- the risk that the Company does not obtain the substantial additional funding required to conduct research and development of its product candidates;

-- 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 important strategic collaborations, including its current collaboration with Genentech, and the risk that any such collaborators will not perform adequately;

-- competitive pressures; and

-- other risk factors identified in the Quarterly Report on Form 10-Q for the Quarter ended September 30, 2007 and other filings that the Company periodically makes with the Securities and Exchange Commission.

In addition, any forward-looking statements represent the 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.

SOURCE: Curis, Inc.

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