

Curis Announces GDC-0449 Phase I Clinical Data Presented at AACR Annual Meeting 2008

Study demonstrates anti-tumor activity in advanced basal cell carcinoma patients

CAMBRIDGE, Mass., Apr 14, 2008 (BUSINESS WIRE) -- Curis, Inc. (NASDAQ: CRIS), a drug development company focused on developing proprietary targeted medicines primarily for cancer treatment, announced that a presentation entitled, "Efficacy data of GDC-0449, a systemic Hedgehog (Hh) pathway antagonist, in a first-in-human, first-in-class, phase I study with locally advanced (LA), multifocal (MF) or metastatic (met) basal cell carcinoma (BCC) patients (pts)," was given by Daniel D. Von Hoff, M.D. today at the American Association for Cancer Research (AACR) Annual Meeting 2008 in San Diego, California. GDC-0449 is being developed by Genentech under a collaboration agreement that Curis and Genentech entered into in June 2003.

Data were presented showing activity in BCC patients in a dose escalation Phase I clinical trial. As a result of these data, Genentech initiated the currently ongoing Phase I expansion cohort in advanced BCC patients, which includes patients with locally advanced, multi-focal and metastatic disease. The data presented at AACR were from nine patients that had enrolled in either the Phase I dose escalation or the Phase I expansion cohort as of the conference's February 11th abstract submission date.

"These Phase I study results provide insights into the role of aberrant Hedgehog signaling in basal cell carcinoma," said Curis President and CEO Dan Passeri. "We are especially pleased that oral administration of GDC-0449 demonstrated anti-tumor activity in almost all BCC patients that were treated with the drug, and we are hopeful that GDC-0449 will ultimately be of therapeutic benefit to patients with advanced BCC. Genentech has indicated that it expects to initiate a Phase II clinical trial in advanced BCC during the second half of 2008, and we look forward to providing future updates about this program."

The following data on the nine Phase I patients were reported:

-- In five patients with metastatic BCC to the lungs, two patients had confirmed RECIST partial responses, two have ongoing stable disease and one had progressive disease. RECIST provides standard parameters to be used when documenting patient response for solid tumors.

-- In four patients with clinically evaluable locally advanced or multi-focal BCC, two patients exhibited complete response in subcutaneous masses by physical exam and two patients had improvement in skin lesions.

Metabolic responses by EORTC (European Organisation for Research and Treatment of Cancer) positron emission tomography (PET) metabolic response criteria were achieved in five out of five patients that received PET scans to date. Time on study for all nine patients ranges from 39 days to over 438 days, with a median of over 176 days as of April 5, 2008. In addition, Gli-1, a biomarker for Hedgehog signaling activity, was reduced in all patients. No dose limiting toxicities have been seen with GDC-0449 in the Phase I studies. Some patients experienced a loss of sense of taste, and there has been a small amount of hair loss and weight loss. Genentech has indicated that it expects to present additional Phase I data, including full toxicity data, at the upcoming ASCO Annual Meeting being held in Chicago, Illinois on May 30-June 3.

About the Phase I trial

Genentech began a Phase I dose escalation clinical trial of GDC-0449 in January 2007, which is designed as an open-label study of a systemic Hedgehog antagonist in patients with locally advanced or metastatic cancers that are refractory to standard therapy or for whom no standard therapies exist. The primary objectives of the Phase I trial were to evaluate the safety and tolerability of escalating doses of GDC-0449, to establish the maximum tolerated dose and dose limiting toxicities and to characterize the pharmacokinetic and pharmacodynamic properties of the drug candidate. The initial objectives of the Phase I clinical trial were achieved and, in October 2007, Genentech initiated a Phase I clinical trial expansion cohort to enroll additional advanced BCC patients.

The initial dose escalation Phase I study was a 3+3 design in which patients received dosages of 150, 270, or 540 mg of GDC-0449 orally as a single dose on Day 1 followed by a one week break and then daily continuous dosing beginning on Day 8 for a twenty-eight day period. The Phase I expansion cohort patients are administered 150 mg of GDC-0449 daily continuously beginning on Day 1.

A Phase II clinical trial for the study of GDC-0449 with concurrent chemotherapy and bevacizumab as a first-line therapy for metastatic colorectal cancer is currently preparing for enrollment. In addition to the metastatic colorectal cancer and advanced BCC Phase II trials, Genentech has indicated that it plans to initiate a third Phase II trial in the second half of 2008 for an undisclosed advanced epithelial tumor.

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 Curis' beliefs about the significance of the Phase I study results, Curis' hope that GDC-0449 will be of therapeutic benefit to advanced BCC patients, and statements regarding the timing of future clinical trials and the availability of further data. 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 Annual Report on Form 10-K for the year ended December 31, 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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