Curis Announces GDC-0449 Phase I Clinical Data Presented at American Society of Clinical Oncology Annual Meeting 2008

CAMBRIDGE, Mass., Jun 02, 2008 (BUSINESS WIRE) -- Curis, Inc. (NASDAQ: CRIS), a drug development company focused on seeking to develop the next generation of proprietary targeted medicines for cancer treatment, announced that a presentation entitled, "A First-in-Human, First-in-Class, Phase I Study of Systemic Hedgehog Pathway Antagonist, GDC-0449, in Patients with Advanced Solid Tumors," was given by Patricia LoRusso, D. O., yesterday at the American Society of Clinical Oncology (ASCO) Annual Meeting 2008 in Chicago, Illinois. GDC-0449 is being developed by Genentech under a June 2003 collaboration agreement with Curis.

"This Phase I trial of a first-in-human systemic Hedgehog antagonist signifies an important milestone for Curis," said Curis President and CEO Dan Passeri. "We are especially pleased that GDC-0449 appears to have had an acceptable safety profile in the study patients, while demonstrating promising, albeit early, signs of efficacy, and we look forward to providing additional updates on the Phase II trials."

The primary objectives of the dose escalation 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 (PK) and pharmacodynamic (PD) properties of the drug candidate. The study enrolled nineteen patients with refractory solid tumors who had not responded to prior treatment. Partial responses were achieved in two patients with advanced basal cell carcinoma (BCC), and stable disease was achieved in two patients with adenocystic carcinoma, a rare cancer most commonly found in the salivary glands.

GDC-0449 demonstrated a favorable PK and PD profile with high sustained plasma concentrations and a prolonged terminal half-life of greater than seven days. 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 reported. Gli1, a biomarker of Hedgehog signaling activity, was down modulated greater than2-fold in skin biopsies from 11 of 14 patients analyzed. The clinical investigators concluded that continuous oral dosing of GDC-0449 at 150 mg/day demonstrated an acceptable safety and efficacy profile, having achieved objective responses with clinical benefit.

As a result of these data, GDC-0449 was selected for advancement into further clinical development. A Phase II trial for the study of GDC-0449 in combination with bevacizumab and standard chemotherapy in first line, metastatic colorectal cancer enrolled its first patient in May 2008. Genentech has indicated that two additional Phase II trials in advanced BCC and solid epithelial tumor, respectively, are scheduled to begin in the second half of 2008.

In addition to the Phase I dose escalation trial, a Phase I expansion cohort in advanced BCC patients, which includes patients with locally advanced, multi-focal and metastatic disease, is currently ongoing. Interim data for the expansion cohort were previously presented at the American Association for Cancer Research (AACR) Annual Meeting in April 2008. Of the nine patients enrolled, including the two advanced BCC patients described in the original study discussed above, six patients achieved partial response and two patients achieved stable disease. There was no significant toxicity observed.

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 expected therapeutic benefits of GDC-0449, the Company's plans to develop targeted medicines for cancer treatment, and Company's plans to provide clinical development updates on GDC-0449 in the future. 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 GDC-0449 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 that ended March 31, 2008 and other filings that the Company periodically makes with the Securities and Exchange Commission.

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