Curis Announces Dosing of First Patient in Phase I Clinical Trial of CUDC-101

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Aug. 26, 2008--Curis, Inc. (NASDAQ: CRIS), a drug development company focused on developing next generation proprietary targeted medicines for cancer treatment, today announced that the first patient has been treated in a Phase I clinical trial of CUDC-101, a first-in-class small molecule drug candidate that has been designed as an inhibitor of epidermal growth factor receptor (EGFR), epidermal growth factor receptor 2 (Her2) and histone deacetylase (HDAC). CUDC-101 has been designed to simultaneously inhibit kinase activity of EGFR and Her2 while also interfering with other key drivers of the cancer cell signaling network involved in tumor cell growth and survival through its HDAC inhibitory activity.

"We are very pleased to be participating in a trial with this promising new drug candidate," commented Dr. Anthony W. Tolcher, Director of Clinical Research at South Texas Accelerated Research Therapeutics (START), and lead investigator of the CUDC-101 Phase I trial. "This trial aims to build on preclinical data suggesting that CUDC-101 may have activity across a broad range of cancer types, particularly those that are resistant to currently marketed drugs. We look forward to exploring the potential of CUDC-101 in the clinic."

"This is an important milestone for the company as we focus on advancing our targeted small molecule drug candidates for cancer treatment into the clinic," said Curis President and CEO Dan Passeri. "We believe that CUDC-101's combination of clinically-validated cancer targets in a single agent may represent an important advance in targeted cancer therapy with respect to efficacy and safety. Moreover, single multi-targeted agents may have potentially significant cost advantages over multiple drugs with the same target profile."

The Phase I trial is designed as an open-label dose escalation study of CUDC-101 in patients with advanced, refractory solid tumors. CUDC-101 will be administered on days one to five of a fourteen day cycle. The first patient enrolled in the Phase I study has completed five days of dosing. The primary objectives of the Phase I trial are to evaluate the safety and tolerability of escalating doses of the Phase I molecule and to establish the maximum tolerated dose and dose limiting toxicities. Secondary objectives will be to assess the pharmacokinetics, efficacy and ability of CUDC-101 to inhibit HDAC, EGFR and Her2 in this patient population. The study is expected to be conducted at two sites within the United States and to enroll between 18 and 40 patients across several dose-escalating cohorts. Further trial details are posted at ClinicalTrials.gov.

About Curis' Targeted Cancer Drug Development Programs

The goal of Curis' targeted cancer drug development programs is to rationally design and develop novel, proprietary small molecules that target one or more clinically validated targets or pathways known to play key roles in the development or maintenance of cancer. By focusing on these validated targets, Curis hopes to reduce risk, time and costs associated with the drug development process. Using its targeted cancer drug development platform, Curis has generated single agent, multi-target small molecules that are being designed to combine HDAC inhibition with suppression of targets that include EGFR, Her2, VEGFR, BCR-Abl/Src, MET, CDK, Aurora, RAF and MEK, with a goal of potentially providing enhanced efficacy over existing drugs. The first developmental candidate selected from this multi-target program is CUDC-101, a first-in-class small molecule designed to inhibit EGFR, Her2 and HDAC. Curis is also using its targeted cancer drug development platform to design single agent, single-targeted drug candidates that it believes have the potential to achieve best-in-class status among existing single target drugs. The first candidate to be selected from Curis' single targeted inhibitors is CUDC-305, an orally available, synthetic small molecule inhibitor of heat shock protein 90 (Hsp 90).

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 expected benefits of CUDC-101, the planned development of drug candidates pursuant to the Company's targeted cancer drug development platform and the Company's plans for its phase I trial of CUDC-101 . 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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