

Curis Provides Program Update on Development Candidate CUDC-101 and Its Targeted Cancer Drug Development Platform HDAC Inhibitory Activity Disclosed as a Core Component of Multi-Target New Chemical Entity Platform

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sept. 25, 2007--Curis, Inc. (NASDAQ: CRIS), a drug development company focused on seeking to develop proprietary targeted medicines primarily for cancer treatment, today provided an update on CUDC-101 and other preclinical drug candidates under its Targeted Cancer Drug Development Platform. The Company is currently developing a number of small molecule multi-target inhibitor drug compounds, including CUDC-101. Each compound is designed to inhibit one or more validated cancer targets, such as Hsp90, Bcr-Abl/Src, CDK, BCL, MEK, VEGF and others along with inhibition of histone deacetylase, or HDAC, a validated non-kinase cancer target.

CUDC-101 is the Company's lead multi-target inhibitor drug candidate under development. CUDC-101 is designed to inhibit EGFR and Her2, two validated cancer targets, as well as HDAC. The Company believes that CUDC-101 is the first-in-class compound under development to simultaneously inhibit HDAC, EGFR and Her2.

The Company is today also disclosing for the first time the identity of HDAC as a core target in all of its multi-target inhibitor drug programs. HDAC had to date been referred to only as "Target A" in order to better preserve Curis' competitive position. Curis had filed a series of provisional patent applications covering its Targeted Cancer Drug Development Platform in September 2006. Applicable patent law provides Curis with a one-year period to bolster such provisional patent applications with additional data before filing the final utility patents, which have now been filed. Curis' patent filings include a broad omnibus application that covers the drug design concept that is the basis for the Targeted Cancer Drug Development Platform as well as numerous species filings relating to specific classes of compounds which Curis believes will constitute novel compositions from a patentability standpoint. Curis expects that it will continue to file additional patent applications covering new compositions in the future.

"We believe that HDAC inhibition is a very promising non-kinase target for cancer therapy. Currently there is one FDA-approved HDAC inhibitor and several other HDAC targeted drug candidates in clinical trials for cancer," said Daniel Passeri, Curis' President and Chief Executive Officer. "There is substantial preclinical evidence demonstrating synergistic induction of cancer cell death between HDAC inhibitors and a diverse range of other targeted therapies or standard chemotherapeutic agents, potentially making HDAC inhibition more broadly effective in the treatment of cancer when integrated with other inhibitory activities. This has led to clinical trials exploring these potential synergistic benefits. Under our Targeted Cancer Drug Development Platform, Curis scientists noted that the active component of several HDAC drug compounds appears to be well-suited for integrating into the core chemical structure of other cancer drugs. Using this insight, we have created a platform of preclinical small molecules that are designed to inhibit HDAC and at least one other validated cancer target in order to simultaneously inhibit these respective targets in the tumor cells. The particular targets have been selected for their potential for synergistic mechanism of action with HDAC to potentially target multiple kinds of cancers. For example, in CUDC-101, we believe that the inhibition of HDAC in cancer cells results in greater sensitization to EGFR and Her2 inhibition, leading to increased cancer cell death. We believe that our single compound approach may address some of the limitations of current therapies by potentially providing enhanced potency, lower toxicity and greater synergies than a combination of single agents. Furthermore, the results of our preclinical testing suggest that our multi-target approach also has the potential to reduce the occurrence of drug resistance."

Although numerous multi-targeted kinase drugs are currently in development by other parties, Curis believes that its platform approach of integrating inhibitory activities against various validated targets with HDAC inhibition in single small molecules is unique. The novel approach of multiple targeted inhibitory activities in a single drug compound may have advantages not only in efficacy and toxicity, but may also be more cost-effective and convenient as compared to the administration of multiple separate agents. The Company is hopeful that CUDC-101's unique multi-target inhibitory activities may ultimately provide some clinical benefit in the future to patients as a monotherapy or in combination with other cancer treatments.

Summary of Preclinical Data

Curis has generated significant in vitro and in vivo preclinical data to support ongoing CUDC-101 preclinical development efforts. "In vitro" refers to the technique of performing a given experiment in a controlled environment outside a living organism, such as in a cell culture. "In vivo" refers to experimentation done in the tissue of an animal.

CUDC-101 displays anti-proliferation and apoptosis, or programmed cell death, inducing activities in vitro against a broad range of cancer cell types including lung, breast, prostate, colon, liver and pancreas. In thirty of these tumor cell line proliferation assays, CUDC-101 exhibits equal (in three cell lines) or greater (in twenty-seven cell lines) potency than several FDA approved targeted cancer drugs alone or in combination, including an HDAC inhibitor in combination with either an EGFR kinase inhibitor or an EGFR/Her2 kinase inhibitor. Potency improvements ranged from 3- to 20-fold for the twenty-seven cell lines in which CUDC-101 demonstrated greater potency.

CUDC-101 also inhibits the in vivo growth of various human cancers in eleven standard mouse tumor xenograft models in which human cancer cells are transplanted into the mouse, allowing the cancer cells to grow into established tumors. CUDC-101 inhibits all three targeted pathways and induces growth inhibition or tumor regression against diverse cancer types in various mouse xenograft models of human cancer.

A favorable safety profile of CUDC-101 was also observed in preclinical studies including non-GLP toxicology studies in various species and with in vitro assays against a standard panel of major receptors, channels and enzymes considered clinically relevant for safety assessments. These results support the Company's belief that CUDC-101 is potentially suitable for future clinical development for various cancer indications.

Potential Upcoming Milestones

CUDC-101

The Company has been actively working toward its goal of filing an IND for CUDC-101 by the end of the first quarter of 2008. Pre-formulation studies have been completed and other IND-enabling studies are currently under way. Preliminary preclinical toxicology studies have shown CUDC-101 to be well tolerated and Curis expects that formal toxicology testing will be initiated early in the fourth quarter of 2007.

While preparing for an IND filing for CUDC-101, the Company has concurrently engaged in potential collaboration discussions with several companies and remains optimistic that it has the potential to consummate a collaboration for CUDC-101 during the second half of 2007 or early 2008, although Curis can not assure that such a collaboration will occur in the time frame expected, or at all. When evaluating potential collaborative opportunities, Curis is seeking a corporate collaboration that will provide Curis with the opportunity for significant involvement in at least the early stages of human clinical testing.

Other Targeted Cancer Drug Development Platform Programs

While Curis seeks to advance CUDC-101 towards IND filing, the Company is also continuing to seek to advance other small molecule drug candidates in its Targeted Cancer Drug Development Platform. Currently, the more advanced of these programs include a multi-target inhibitor that is designed to inhibit HDAC, Bcr-Abl and Src kinases, and another that seeks to inhibit HDAC and Hsp90.

The Company anticipates that it will select a second compound from this platform as a development candidate in late 2007. Assuming that Curis meets this selection date and that subsequent IND-enabling preclinical studies are successful, the Company anticipates that it would file an IND for this second development candidate by the end of 2008. The Company currently also plans to select a third development candidate from this platform in 2008.

Webcast and Conference Call

The Company will hold a webcast and conference call today, September 25, 2007, at 10:00 A.M. Eastern Time, to provide program updates for CUDC-101 and the other drug programs that Curis is seeking to develop under the Targeted Cancer Drug Development Platform, including the importance of HDAC inhibition to these drug programs. Daniel Passeri, President and Chief Executive Officer of Curis, will host the call.

The webcast can be accessed live at the investor relations section of Curis' web site at www.curis.com. The webcast will be archived and available for replay until 5:00 p.m. Eastern Time on November 24, 2007. The audio portion of the webcast will also be simultaneously broadcast telephonically and will be followed by a question and answer period. Access numbers for the live telecom and question and answer period are as follows: (888) 396-2369 (U.S./Canada) and (617) 847-8710 (international); Conference ID number is 29936939.

A telephonic replay of the webcast will be available beginning at 2:00 p.m. Eastern Time on September 25, 2007 through 5:00 p.m. Eastern Time on November 24, 2007. Access numbers for this replay are: (888) 286-8010 (U.S./Canada) and (617) 801-6888 (international); Conference ID number is 82961173.

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, the Company is building upon its previous experiences in targeting signaling pathways in the areas of cancer, neurological disease and cardiovascular disease. For more information, visit 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 statements regarding the potential of HDAC to serve as an effective target for cancer therapy, the expected results of further preclinical testing of the Company's multi-target inhibitor compounds, the expected anti-cancer benefits of such compounds, including when compared to single-agent cancer therapies, the Company's statements regarding its plans to further develop and file an IND for CUDC-101 and one or more other compounds under its Targeted Cancer Drug Development Platform, and its plans to seek a collaborator for such programs and the expected terms of any such collaboration. 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 factors that may cause the Company's 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 and its strategic collaborators' and licensees' product development programs, including without limitation adverse events, difficulties with patient enrollment and other unplanned delays in its Hedgehog pathway antagonist program currently under Phase I clinical development with Genentech and unplanned delays and/or failures in the Company's efforts to advance its preclinical Targeted Cancer Drug Development Platform programs, including CUDC-101;
- difficulties or delays in obtaining or maintaining required regulatory approvals for products being developed by the Company and its collaborators and licensees;
- the Company's 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 the Company's inability to execute, its business plan;
- the risk that Curis does not obtain the additional funding required to conduct research and development of its product candidates and execute its business plan;

- 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;
- risks relating to the Company's ability to enter into and maintain important strategic collaborations, and the risk that its current and future collaborators and licensees will not perform adequately, including such risks with respect to its current collaboration agreements with Genentech and Wyeth;
- competitive pressures; and
- other risk factors identified in the Company's most recent Current Report on Form 10-Q and its other reports periodically filed 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 its views as of any subsequent date. The Company 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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