Curis Selects Hsp90 Inhibitor CUDC-305 as Development Candidate from Targeted Cancer Drug Development Platform

CUDC-305 meets key preclinical criteria for advancement

CAMBRIDGE, Mass., Jul 21, 2008 (BUSINESS WIRE) -- Curis, Inc. (NASDAQ: CRIS), a drug development company focused on seeking to develop the next generation of targeted small molecule drug candidates for cancer treatment, today announced that the Company has selected an orally available, synthetic small molecule inhibitor of heat shock protein 90 (Hsp90) as a development candidate from its targeted cancer drug development platform. In addition to demonstrating potent efficacy across a broad range of cancers in preclinical cancer models, CUDC-305 exhibits promising pharmacological features, particularly its high oral bioavailability, high tumor penetration and extended tumor retention.

"Hsp90 has become a target of great interest in the field of cancer therapeutics," said Curis President and CEO Dan Passeri. "We are pleased to enter this field with our own novel and proprietary compound, CUDC-305, which not only has met our rigorous internal metrics for development candidate selection, but has also demonstrated pharmacological properties that, while based upon early results, we believe may enable it to achieve best-in-class among Hsp90 inhibitors. We have initiated early, but promising, discussions with several pharmaceutical companies regarding a potential collaboration as we seek to continue to advance this candidate towards the clinic. We expect to initiate IND-enabling studies shortly and anticipate that, assuming the outcome of those studies is favorable, we will file an IND application for CUDC-305 in mid-2009."

In both laboratory and animal testing, CUDC-305 demonstrated high potency in vitro and/or in vivo across a wide range of cancers. Most notably, Curis scientists observed complete tumor regression following oral administration of CUDC-305 in a mouse xenograft model of acute myelogenous leukemia (AML). Tumor regression has also been observed after treatment of CUDC-305 in mouse xenograft models of breast, non-small cell lung, gastric cancer and glioblastoma brain cancers. In this preclinical testing, the compound also demonstrated an ability to effectively cross the blood brain barrier, and demonstrated an ability to extend survival in an intracranial glioblastoma model. Early stage toxicity studies suggest that CUDC-305 appears to have a better therapeutic window than several leading Hsp90 inhibitors in clinical development.

About Hsp90

Hsp90 is a member of a class of proteins called molecular chaperones that play a fundamental role in the folding, stabilization and degradation of other cellular proteins, or clients, under normal or stressful conditions. Hsp90, in particular, has become an attractive therapeutic target for the treatment of cancer because a majority of its client proteins are involved in cellular signaling transduction and have been identified as potential contributors to various aspects of cancer cell growth and survival. Inhibitors of Hsp90 activity may be of therapeutic value if they can prevent Hsp90 proteins from protecting the particular client proteins involved in cancer and allow them to be degraded, thereby inducing cancer cell death.

About Curis' Targeted Cancer Drug Development Platform

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 this multi-targeted inhibitor platform, Curis has generated single small molecules that combine HDAC inhibition with suppression of targets that include EGFR, Her2, VEGFR, BCR-Abl/Src, MET, CDK, Aurora, RAF and MEK, to potentially provide enhanced efficacy over existing drugs. The first developmental candidate selected from this program is CUDC-101, a first-in-class small molecule inhibitor of EGFR, Her2 and HDAC. An investigational new drug application for CUDC-101 was accepted in June 2008 and the first patient is expected to be treated in the third quarter of 2008. In addition, Curis' targeted cancer drug development program includes single targeted drugs designed and developed to potentially achieve best-in-class status. The first candidate to be selected from Curis' single targeted inhibitors is CUDC-305.

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 Curis' beliefs about the potential efficacy, potency and pharmacological features of CUDC-305, Curis' belief that CUDC-305 has the potential to be of superior therapeutic benefit among Hsp90 inhibitors, Curis' plans to enter into a collaboration for the development of CUDC-305, Curis' expectation that it will file an IND application with FDA in mid-2009 and Curis expectations regarding the potential benefits of its targeted cancer drug development programs. 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:

-- The Company may experience adverse results, delays and/or failures in its internal product development programs, including without limitation unplanned delays and/or failures in its ability to further advance its product candidates, CUDC-101 and CUDC-305, and any other programs under its targeted cancer drug development platform. For example, the Company faces the risk

that future clinical trials and any further preclinical testing of such development candidates will not demonstrate the results shown to date.

-- The Company's collaborator, Genentech, may experience adverse results, delays and/or failures in the Hedgehog pathway antagonist program currently under clinical development and the Company may have no control over, or foreknowledge of, the progress of this program.

-- The Company may experience difficulties or delays in obtaining or maintaining required regulatory approvals for products under development both internally and through its Hedgehog antagonist collaboration with Genentech.

-- The Company may not be able to obtain or maintain the patent and other proprietary intellectual property protection necessary for the development and commercialization of products based on its technologies.

-- There may be adverse changes in the Company's ability to execute, its business plan.

-- The Company may not be able to obtain the substantial additional funding required to conduct research and development of its product candidates.

-- The Company may experience 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.

-- The Company faces risks relating to its ability to enter into and maintain planned collaborations for development candidates under its targeted cancer drug development programs, its ability to maintain its current collaborations with Genentech and the risk that any such collaborators will not perform adequately.

-- The Company may experience competitive pressures.

The Company also faces other risk factors identified in the Quarterly Report on Form 10-Q for the quarter ended March 31, 2008 and other filings that it 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.

Curis, Inc.
Michael P. Gray, 617-503-6632
Chief Financial Officer
mgray@curis.com
