Curis Announces Preclinical Efficacy Data for CUDC-305 at EORTC-NCI-AACR Symposium

CUDC-305 demonstrates efficacy in solid tumor and hematological preclinical cancer models

CAMBRIDGE, Mass.--(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 presented a poster entitled, "CUDC-305, a novel, synthetic Hsp90 inhibitor with unique pharmacological properties" at the 20th European Organization for Research and Treatment of Cancer (EORTC)- National Cancer Institute (NCI)-American Association for Cancer Research (AACR) Symposium on "Molecular Targets and Cancer Therapeutics" in Geneva, Switzerland.

"We are pleased to report the progress of our proprietary Hsp90 inhibitor, CUDC-305, as we continue to advance it towards the clinic," said Curis President and CEO Dan Passeri. "The compound was designed to optimize or improve pharmacological properties that we believe collectively make this a strong drug candidate and potentially a best-in-class therapeutic. The preclinical data demonstrates efficacy in both solid tumors and hematological cancers with a potential niche in the area of brain cancer. We look forward to continuing to provide updates on this novel compound."

The poster highlighted data demonstrating that CUDC-305 appears to have a strong combination of pharmacological properties that may contribute to its potent efficacy in preclinical cancer models. In preclinical xenograft mouse models, the orally administered compound exhibited high oral bioavailability and a prolonged terminal half-life of 20.5 hours in tumors. In addition, brain pharmacokinetic data demonstrates that CUDC-305 is highly brain penetrable suggesting that the compound may have potential advantages for the treatment of primary or metastatic brain cancers.

In a mouse xenograft model for brain cancer wherein tumor cells derived from a human glioblastoma were implanted subcutaneously, CUDC-305 exhibited dose-dependent inhibition of tumor growth. The poster included pharmacodynamic data following this efficacy study demonstrating upregulation of Hsp70 expression, a biomarker of Hsp90 inhibitor activity, and downreglation of cancer biomarkers including cMET, cyclin D1 and RAF-1 protein levels in addition to AKT signaling. Tumors were also collected for immunohistochemisty analysis revealing a dose-dependent reduction of cell proliferation and micro-vessel density, which is indicative of an anti-angiogenesis effect. Furthermore, in a separate mouse xenograft study in which glioblastoma tumor cells were implanted intracranially, CUDC-305 treatment significantly prolonged survival in treated mice.

The poster also provided data demonstrating potent in vitro anti-proliferative activity across a diverse range of preclinical cancer cell lines representing both solid tumor and hematological malignancies using dosages well below concentrations effective in mouse xenograft models. In a hematological mouse xenograft model, CUDC-305 demonstrated the ability to induce complete tumor regression following a three week dosing regimen while maintaining a favorable safety profile.

The Company anticipates filing an IND application for CUDC-305 in mid-2009 and is currently involved in discussions with several pharmaceutical companies for a potential collaboration for the continued development of this compound.

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, 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' belief that CUDC-305 may have therapeutic benefit for solid tumor and hematological indications including brain cancer, 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 June 30, 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.
