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Curis and Debiopharm Announce Initiation of Phase I-II Clinical Study of HSP90 Inhibitor Debio 0932

Study to Test Debio 0932 in Patients With Advanced Non-Small Cell Lung Cancer

LEXINGTON, Mass. and LAUSANNE, Switzerland, Aug. 15, 2012 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), a drug development company seeking to develop proprietary targeted medicines for cancer treatment, and Debiopharm Group (Debiopharm), a group of companies with a focus on the development of prescription drugs that target unmet medical needs, today announced that Debiopharm has begun treating patients in its HALO Phase I/II clinical trial of orally-administered Heat Shock Protein 90 (HSP90) inhibitor Debio 0932 in combination with chemotherapy regimens in patients with advanced stages of non-small cell lung cancer (NSCLC).

"Our team is pleased to report that we have successfully advanced Debio 0932 into a large clinical trial to study its potential to provide benefit to patients suffering from non-small cell lung cancer," said Rolland-Yves Mauvernay, President and Founder of Debiopharm Group, who added: "We believe that HSP90 represents an important molecular target in cancer therapy in general and in lung cancer in particular. We expect this Phase I-II study as well as the ongoing Phase Ib clinical trial to yield key data that will guide this important molecule's further development."

"Debiopharm has generated a body of clinical data with Debio 0932 to date, showing that it is generally well tolerated and that the molecule demonstrates signs of clinical activity, including a confirmed partial response that was observed in a patient with K-ras-mutated lung cancer," said Dan Passeri, Curis' President and Chief Executive Officer. "We believe that these data demonstrate the potential of Debio 0932 and our HSP90 inhibitor technology, and importantly, Curis is eligible for future milestone payments based on the successful achievement of specific clinical development and regulatory approval objectives under this collaboration."

About the HALO Study

The HALO (HSP90 inhibition And Lung cancer Outcomes) study is a Phase I-II clinical trial of the safety and efficacy of the oral HSP90 inhibitor Debio 0932 in combination with standard of care (SOC) agents in first- and second-line therapy of patients with advanced NSCLC.

On August 10, 2012, Debiopharm initiated the Phase I portion of this clinical trial designed to determine the recommended Phase II dose of Debio 0932 in combination with various chemotherapy regimens in patients with stage IIIb or IV NSCLC with disease that is characterized as wild-type EGFR (Epidermal Growth Factor). Debio 0932 will be administered in this study in combination with cisplatin/pemetrexed and cisplatin/gemcitabine in treatment-naïve patients, and with docetaxel in previously treated patients.

Once a recommended Phase II dose of Debio 0932 in combination with each of the 3 chemotherapy regimens described above has been identified, the randomized, double-blind, placebo-controlled Phase II portion of this study will then begin where approximately 140 eligible patients will be randomized to receive chemotherapy with either placebo or Debio 0932. The primary objective of the Phase II study is to determine the efficacy of Debio 0932 in combination with chemotherapy. The KRAS mutation status will also be assessed and used as a stratification factor.

About Debio 0932

HSP90 is a chaperone protein that controls the folding and processing of certain client proteins. HSP90 clients include many proteins that drive tumor development and progression, such as EGFR, HER2, c-MET, AKT, KIT, FLT3, and VEGFR. Inhibition of HSP90 leads to degradation of client proteins targeting multiple oncogenic signaling pathways.

Debio 0932 is an oral second-generation HSP90 inhibitor, which has shown extended tumor retention, blood-brain-barrier penetration, and promising anti-tumor activity both as monotherapy and in combination against a broad range of tumors in pre-clinical models.

Debiopharm presented data from the dose escalation portion of an ongoing Phase I clinical trial study at the annual meeting of the American Society of Clinical Oncology in June 2012. Debio 0932 was generally well tolerated in this study and showed

promising signs of anti-tumor activity in patients with advanced solid tumors, especially lung cancer. For further details see www.debiopharm.com/press-releases/. Debiopharm advanced Debio 0932 into the Phase Ib expansion portion of the study in the beginning of 2012. The objectives of this ongoing Phase Ib portion of the study are to further assess the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932, and to make a preliminary assessment of anti-tumor activity in patients with advanced solid tumors, including patients with NSCLC.

In preclinical testing Debio 0932 demonstrated potent anti-proliferative activity against a broad range of cancer cell lines, including many NSCLC cell lines which are resistant to SOC agents. Debio 0932 potently inhibits tumor growth in subcutaneous xenograft models of a number of solid and hematological malignancies, including models of NSCLC which harbor mutations conferring acquired or primary erlotinib resistance. Furthermore, Debio 0932 is able to extend animal survival in models of brain metastasis due to its ability to cross the blood-brain barrier, and it enhances the activity of several SOC agents in animal models of cancer.

About Debiopharm Group™

Debiopharm Group™ (Debiopharm) is a Swiss based global biopharmaceutical group of companies with a focus on the development of prescription drugs that target unmet medical needs. The group in-licenses, develops and/or co-develops promising biological and small molecule drug candidates having reached clinical development phases I, II or III, as well as earlier stage candidates. It develops its products for global registration and maximum commercial potential. The products are out-licensed to pharmaceutical partners for sales and marketing. Debiopharm is also active in the field of companion diagnostics with a view to progressing in the area of personalized medicine. Debiopharm independently funds the worldwide development of all of its products while providing expertise in pre-clinical and clinical trials, manufacturing, drug delivery and formulation, and regulatory affairs. For more information on Debiopharm Group™, please visit www.debiopharm.com.

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. Curis is building upon its previous experiences in targeting signaling pathways, including the Hedgehog pathway, in its effort to develop proprietary targeted cancer programs. For more information, visit Curis' website at www.curis.com.

The Curis, Inc. logo is available at <http://www.globenewswire.com/newsroom/prs/?pkgid=11347>

Cautionary Note Regarding Forward-Looking Statements: *This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation statements regarding Debio 0932's potential benefit to patients with advanced stages of non-small lung cancer. Forward-looking statements used in this press release may contain the words "believes", "expects", "anticipates", "plans", "seeks", "estimates", "assumes", "will", "may," "could" 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. For example, Debiopharm may not be able to successfully enroll patients in the Phase Ib or Phase I/II studies, Debiopharm may experience delays, setbacks and failures in its clinical development of Debio 0932, and Debio 0932 may cause unexpected toxicities. Moreover, positive results in preclinical studies of Debio 0932 may not be predictive of similar results in human clinical trials, and promising results from early clinical trials of Debio 0932 may not be replicated in later clinical trials.*

Curis also faces other important risks relating to its business, operations, financial condition and future prospects generally, that are discussed in its Quarterly Report on Form 10-Q for the quarter ended June 30, 2012 and other filings that it 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 Curis' 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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