

Curis and Debiopharm Group™ Announce Initiation of Phase I Dose Finding Clinical Study With a Combination of HSP90 Inhibitor Debio 0932 and Everolimus Designed to Target Advanced Metastatic Renal Cell Carcinoma, the Study Will Determine the Maximum Tolerated Dose of Debio 0932 in Combination With Everolimus

LAUSANNE, Switzerland and LEXINGTON, Mass., Oct. 22, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology focused company developing novel, targeted drug candidates for the treatment of human cancers, and Debiopharm Group™ (Debiopharm), a Swiss-based global biopharmaceutical group of companies with a focus on the development of prescription drugs that target unmet medical needs, including oncology as well as companion diagnostics, today announced the start of an open-label, multicenter Phase I dose-finding study of Debio 0932, a heat shock protein 90 (HSP90) inhibitor in combination with everolimus, an inhibitor of mammalian target of rapamycin (mTOR) in patients with advanced or metastatic renal cell carcinoma (RCC), who have been previously treated with a VEGF-directed tyrosine kinase inhibitor.

This dose escalation study is designed to determine the safety and maximum tolerated dose of Debio 0932 in combination with everolimus, in previously treated patients with advanced/metastatic RCC. The pharmacokinetic profiles and any potential drug-drug interactions between the two agents will also be assessed. The trial also includes an expansion cohort of 25 patients with metastatic clear cell RCC. While approved monotherapy treatments for RCC, including mTOR inhibitors are active, improved therapies are needed to enhance the depth and duration of response. Several mTOR signaling pathway components such as mTOR, AKT and LKB1 are HSP90 client proteins. Mechanistic data suggest the potential for improved efficacy through dual mTOR and HSP90 inhibition, which may also prevent the development of acquired resistant to this cancer therapy.

"We are very pleased that this phase I study has kicked off and believe that the combination of our compound with everolimus can potentially further improve the outcome for patients suffering from RCC," said Rolland-Yves Mauvernay, President and founder of Debiopharm Group™.

"We continue to be impressed with Debiopharm's systematic approach in developing Debio 0932 for the treatment of cancers where it is shown to have a strong scientific rationale and supportive preclinical data. We believe that potent inhibition of HSP90 by Debio 0932 with its promising safety profile and convenient oral dosing, in combination with everolimus has the potential to provide improved benefit for patients with kidney cancers," said Ali Fattaey, Ph.D., President and Chief Operating Officer of Curis.

About RCC

RCC represents approximately 2-3% of all adult malignancies, and is the seventh most common cancer in men and the ninth most common cancer in women. The European Society of Medical Oncology (ESMO) estimates approximately 209,000 new cases and 102,000 deaths due to renal cell carcinoma per annum worldwide. In the United States, according to the National Cancer Institute's Surveillance Epidemiology and End Results (SEER) database, approximately 65,000 new cases and more than 13,500 deaths from kidney and renal pelvic cancers are expected in 2013.

About Debio 0932

Debio 0932 is a synthetic small molecule that belongs to the HSP90 family inhibitors. It competes with ATP in binding to the N-terminal portion of HSP90 and inactivates the ATPase activity of the chaperone. Inhibition of HSP90 results in an increased degradation of oncogenic proteins resulting in tumor growth inhibition.

In several pre-clinical tumor models, Debio 0932 exhibited potent antitumor activity against a broad range of cancers. In renal cell carcinoma (RCC) in vitro tumor models, Debio 0932 combined with sorafenib, sunitinib or everolimus showed significant additive to synergistic activity in different cell lines. These findings were confirmed in vivo. In a patient-derived in vivo RCC xenograft model, Debio 0932 combined with everolimus demonstrated additive to synergistic antitumor activity.

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 access to the largest number of patients worldwide. 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 about Debiopharm Group™, please visit: www.debiopharm.com.

About Curis, Inc.

Curis is an oncology focused company seeking to develop, targeted drug candidates for the treatment of human cancers. Erivedge® is the first and only FDA-approved medicine for the treatment of advanced basal cell carcinoma and is being commercialized and developed by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech. Debio 0932, an oral HSP90 inhibitor is being developed by Curis' collaborator, Debiopharm, for multiple oncology indications. Curis is leveraging its experience in targeting signaling pathways to develop proprietary targeted cancer programs including CUDC-427, a small molecule antagonist of IAP proteins, and CUDC-907, a dual PI3K and HDAC inhibitor.

For more information, visit Curis' website at www.curis.com.

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 renal cell carcinoma. 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 this Phase I study, 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. Debiopharm may not achieve projected research, development and commercialization goals in its expected time frames.

Curis also faces other important risks relating to, among other things, the successful development and commercialization of its and its collaborators' product candidates and 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, 2013 and other filings that it periodically makes with the Securities and Exchange Commission.

Any forward-looking statements in this press release speak only as of the date hereof. Curis disclaims obligation to update any forward-looking statements except to the extent required by law.

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