Debiopharm and Curis Announce Initiation of Phase Ib Expansion Study of HSP90 Inhibitor Debio 0932

Lausanne, Switzerland and Lexington, Mass., USA, February 16, 2012 -- 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 a Phase Ib clinical trial of Heat Shock Protein 90 (HSP90) inhibitor Debio 0932. Debiopharm recently successfully completed a Phase Ia dose escalation study with Debio 0932 and has indicated that it expects to initiate a combination Phase I/II study in non-small cell lung cancer patients in the second quarter of 2012.

“Our team has been very pleased with the development of Debio 0932, which has become an important molecule in Debiopharm’s pipeline,” said Rolland-Yves Mauvernay, President and Founder of Debiopharm Group. “We believe that HSP90 represents an important molecular target in cancer therapy, and we are eager to advance this molecule in the Phase Ib clinical trial, as well in our planned Phase I/II studies, which we hope will yield important new data for the further development of Debio 0932.”

“We have been highly impressed with the depth of Debiopharm’s development expertise and commitment to furthering Debio 0932 into additional clinical studies in 2012,” said Dan Passeri, Curis President and Chief Executive Officer. “Importantly, we continue to be very pleased with the clinical results that have been observed to-date, and we look forward to reporting further progress on this molecule in the future.”

About the Phase I Clinical Trial
Debiopharm initiated a Phase I clinical trial in April 2010 that was designed to evaluate the maximum tolerated dose and safety of Debio 0932. The first part of the study (Phase Ia), an open-label, multi-center dose escalation trial evaluating the safety and tolerability of escalating multiple dose levels of Debio 0932 given daily or every other day as a single agent by oral administration in patients suffering from advanced solid tumours, was recently completed.

Debio 0932 was generally well tolerated, with no evidence of ocular or liver toxicity, and showed promising signs of efficacy in patients with advanced solid tumours. The recommended dose, established at 1000mg every day, will be tested in additional patients during the expansion phase (Phase Ib) of the ongoing Phase I study. Details from the Phase Ia portion of the study will be presented at a medical conference in 2012.

Debiopharm expects to treat approximately 30 patients as part of the Phase Ib expansion study. The objectives of this study will be to further assess the safety profile, pharmacokinetics and pharmacodynamics of Debio 0932 at the recommended dose level and regimen, and to further assess anti-tumour activity in patients with advanced solid tumours, including patients with non-small cell lung cancer.

About Debio 0932
Debio 0932 is a novel heat shock protein 90 (HSP90) inhibitor with strong affinity for HSP90 α/β, high oral bioavailability and potent anti-proliferative activity against a broad range of cancer cell lines (with
a mean IC50 of 220 nmol/L), including many non–small cell lung cancer (NSCLC) cell lines which are resistant to standard-of-care (SOC) agents. Debio 0932 potently inhibits tumour growth in subcutaneous xenograft models of a number of solid and haematological malignancies, including models of NSCLC which harbour 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 standard-of-care 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 personalised 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 signalling pathway drug technologies to seek to create new targeted small molecule drug candidates for cancer. Curis is building upon its previous experiences in targeting signalling pathways, including the Hedgehog pathway, in its effort to develop proprietary targeted cancer programs. 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: our belief that HSP90 is an important molecular target in cancer, our expectations for timing of the initiation of a Phase I/II study of Debio 0932 in non-small cell lung cancer and our expectations that Phase Ia data will be presented at a medical conference in 2012. 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 enrol 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 September 30, 2011 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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