Curis Announces Initiation of a Roche-Sponsored Phase 1b/2 Study of Erivedge(R) (vismodegib) in Relapsed/Refractory AML and High Risk MDS

AML and MDS Represent Non-Mutation Driven Hedgehog Pathway Malignancies

LEXINGTON, Mass., Oct. 4, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused company developing novel drug candidates for the treatment of human cancers, today announced that Roche initiated a Phase 1b/2 study of Erivedge® (vismodegib) in patients with relapsed/ refractory acute myelogenous leukemia (AML) and relapsed/refractory high-risk myelodysplastic syndrome (MDS). Roche and its wholly-owned subsidiary, Genentech, have developed Erivedge under a collaboration agreement with Curis.

Aberrant activation of the Hedgehog signaling pathway has been reported to play a role in the development of certain cancers including basal cell carcinoma (BCC) and AML. Erivedge is an oral drug designed to block abnormal Hedgehog pathway signaling, and has been approved for the treatment of advanced basal cell carcinoma (aBCC) in the US, Europe and a number of other countries. The current Phase 1b/2 clinical trial is designed to examine the potential benefit from Erivedge treatment for AML and MDS cancer patients. It is believed that selective targeting and blocking of the Hedgehog signaling pathway may have an effect on leukemic (stem) cell proliferation and survival.

"We are extremely pleased with Roche's commitment to the continued development of Erivedge for treatment of patients with cancers where the Hedgehog pathway appears to be altered," said Ali Fattaey, Ph.D., Curis' President and Chief Operating Officer. "We believe that inhibition of Hedgehog pathway signaling by Erivedge has the potential to provide benefit for patients with AML and MDS. Specifically, unlike basal cell carcinomas that are driven by mutations in the Hedgehog pathway, AML and MDS represent cancers where ligand-dependent abnormal signaling within this pathway is associated with the disease."

About the Phase 1b/2 AML/MDS study:

The Phase 1b/2 study is designed to investigate the safety and efficacy of Erivedge in patients with relapsed/ refractory AML or relapsed/refractory high risk MDS. According to Roche, the open-label, non-randomized study is expected to enroll approximately 60 patients into two cohorts. Patients in Cohort 1 will receive 150 milligrams of Erivedge alone once daily, and patients in Cohort 2 will receive the same dose of Erivedge once daily in combination with the standard dose of cytarabine administered for 10 days. The primary endpoint of the trial is the overall response rate after 8 weeks of treatment. The secondary endpoints include overall response rate at any time during treatment, duration of response, overall survival, and safety and pharmacokinetics of the study drug(s). For additional details of the study, please refer to www.clinicaltrials.gov(study identifier: NCT01880437).

About Erivedge

Erivedge is designed to selectively target the Hedgehog signaling pathway, which is implicated in the development of certain types of cancer, including basal cell carcinoma (BCC).

Roche has developed Erivedge under a collaboration agreement with Curis. Erivedge was discovered by Genentech and jointly validated by Genentech and Curis through a series of preclinical studies. Through this collaboration, Genentech (U.S.), Roche (ex-U.S. excluding Japan) and Chugai Pharmaceuticals (Japan) are responsible for the clinical development and commercialization of Erivedge. Curis is eligible to receive cash payments assuming the successful achievement of specified clinical development and regulatory approval milestones, as well as royalties upon commercialization of Erivedge.

In January 2012, Erivedge became the first licensed medicine for patients with advanced basal cell carcinoma when the U.S. Food and Drug Administration (FDA) approved it following a priority review. Erivedge has since also been approved in other countries, including Australia, Canada, Ecuador, European Union, Norway, Israel, Mexico, South Korea, Switzerland and Uruguay.

About Acute Myeloid Leukemia (AML)

AML is the most common acute leukemia in adults, accounting for approximately 25% of all leukemias in adults in the Western world with the highest incidence in the U.S., Australia and Western Europe. Approximately 14,500 new cases and more than 10,000 deaths from the disease are expected in the U.S. in 2013 according to the National Cancer Institute's Surveillance Epidemiology and End Results (SEER) research data.

About Curis, Inc.

Curis is an oncology-focused company seeking to develop novel 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 by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech. Curis is also seeking to further the development of its pipeline of proprietary targeted cancer drug candidates, 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 Statement s

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation statements regarding the potential benefits of treating AML and MDS patients with Erivedge, and clinical development plans and timelines for the Phase 1b/2 trial of Erivedge in AML and MDS. 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, Curis and its collaborators may experience adverse results, delays and/or failures in their preclinical and clinical drug development programs. Curis and its collaborators' drug candidates may cause unexpected toxicities and/or fail to demonstrate sufficient safety and efficacy in clinical trials and may never achieve the requisite regulatory approval needed for commercialization. Curis and its collaborators may not achieve projected research, development and

commercialization goals in the time frames that they publicly announce. Curis will require substantial additional capital to fund the research and development of its drug development programs. Curis may not obtain or maintain necessary patent protection for its programs and could become involved in expensive and time consuming patent litigation and interference proceedings. Curis and its collaborators face substantial competition. Curis is dependent upon its key collaborators and these collaborations may not be scientifically or commercially successful. Unstable market and economic conditions and other factors may adversely affect Curis' financial condition and its ability to access capital to fund the growth of its business. Curis could lose its rights to Erivedge royalties and related royalty payments if its wholly-owned subsidiary defaults under its secured credit agreement with BioPharma-II. Curis' stock price may not appreciate in value. Curis also faces other important risks relating to its business, operations, financial condition and future prospects 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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