Curis Announces the Conditional Approval of Erivedge(R) in the European Union
Triggers $6 Million Milestone Payment to Curis

LEXINGTON, Mass., July 15, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused drug development company seeking to develop novel drug candidates for the treatment of human cancers, today announced that the European Commission has granted conditional approval to Erivedge® (vismodegib) for the treatment of adult patients with symptomatic metastatic basal cell carcinoma (BCC) or locally advanced BCC inappropriate for surgery or radiotherapy. This conditional approval makes Erivedge the first licensed treatment in Europe for patients with advanced BCC, a rare form of skin cancer which can be disfiguring, debilitating and even fatal.

"We are extremely pleased that Erivedge will now be available as the first approved medicine in the European Union (EU) for patients with advanced basal cell carcinoma, a serious medical condition," stated Dan Passeri, Curis' Chief Executive Officer. "Roche's development and commercialization efforts have significantly expanded global patient access and the market opportunity for Erivedge, with regulatory approvals for Erivedge in the United States, Switzerland, Australia, Israel, South Korea, Mexico, and Ecuador, in addition to the EU. We expect that Roche will seek approval of Erivedge in several other territories and anticipate that these efforts will continue to expand the number of patients that will have access to this important medicine in the near future."

The European Commission granted the conditional approval based upon the positive recommendation received in April this year from the Committee of Medicinal Products for Human Use of the European Medicines Agency (EMA). The European Commission's decision will be applicable to all 28 European Union member states. As a result of this conditional approval, Curis earned a $6 million milestone payment from Genentech, a member of the Roche Group, and will continue to be entitled to receive royalties on future sales of Erivedge. Roche is responsible for commercializing Erivedge in the EU.

A conditional marketing authorization is granted to medicinal products with a positive benefit/risk assessment that satisfy an unmet medical need and whose availability would result in a significant public health benefit. Under the provisions of the conditional approval, Roche is expected to provide additional data on Erivedge in advanced BCC from an ongoing global safety study.

About Basal Cell Carcinoma and the Hedgehog Pathway

Basal cell carcinoma (BCC) is the most common type of skin cancer in Europe, Australia and the United States. The disease is generally considered curable if the cancer is restricted to a small area of the skin. In advanced BCC, if the disease is left untreated or recurs in the same location after surgery or radiotherapy, it may progress and spread further into surrounding areas such as sensory organs (ears, nose and eyes), bone or other tissues. Depending on the location of the lesion, some cases of advanced BCC can be disfiguring, and treatment with surgery or radiation can lead to the loss of sensory organs and their functions such as eyesight or hearing.

The Hedgehog signaling pathway plays an important role in regulating proper growth and development in the early stages of life and becomes less active in adults. Abnormal Hedgehog signaling is implicated in more than 90 percent of BCC cases.

About Erivedge

Erivedge is designed to selectively target the Hedgehog signaling pathway, which is implicated in the development of certain types of cancer, including 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 upon 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 under the priority review program that provides for an expedited six-month review of drugs that offer major advances in treatment. Erivedge has since also been approved in Switzerland, Australia, Israel, South Korea, Mexico, and Ecuador.

About the ERIVANCE BCC Study

The EU conditional approval is based on findings from the primary analysis (26 November 2010) in the pivotal ERIVANCE study which enrolled 104 advanced BCC patients (71 had locally advanced and 33 had metastatic disease) from 31 study centers in the U.S., Australia and Europe.

The study showed that Erivedge substantially shrank tumors or healed visible lesions, as defined by objective response rate, in 42.9 percent of patients with locally advanced and 30.3 percent of patients with metastatic disease as assessed by independent review.

The most common adverse events included muscle spasms, hair loss, altered taste sensation, fatigue and weight loss. Serious adverse events (SAEs) were observed in 26 patients (25 percent), however of these only four patients (4 percent) had SAEs that were considered to be related to treatment with vismodegib. Fatal events were reported in seven patients (7 percent) although none were considered by investigators to be related to treatment with Erivedge. In all cases, patients had other pre-existing

diseases or symptoms that were related to their presumed cause of death.

About the STEVIE Study

The safety profile of Erivedge is also being evaluated in the STEVIE study, a global, single-arm, open-label multicenter trial in patients with advanced forms of BCC. The study is designed to enroll 1,200 patients. An interim analysis from STEVIE presented at the American Society of Clinical Oncology's (ASCO) 2013 Annual Conference confirmed a similar safety profile to that observed in the ERIVANCE BCC study.

About Curis, Inc.

Curis is an oncology-focused drug development 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 and developed 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 Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation Curis' expectations regarding: Roche's timelines for launch in various EU countries, Roche's expected regulatory plans for other territories, and the potential expansion of patient access to Erivedge. 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, other foreign regulatory agencies may not view favorably the safety and efficacy profile of Erivedge in the treatment of advanced BCC, in which case Erivedge will not be approved for sales and marketing for the treatment of such indication in markets outside of the United States, EU, Switzerland, Australia, Israel, South Korea, Mexico, and Ecuador. Genentech and Roche may experience delays or failures in the manufacture and/or commercial launch of Erivedge. Erivedge's benefit/risk profile may not be widely accepted by the medical community or third party payors for the treatment of advanced BCC. Regulatory and administrative governmental authorities may determine to delay or restrict Genentech's ability to continue to develop or commercialize Erivedge. Competing drugs may be developed that are superior to Erivedge. Any of the foregoing risks could adversely affect the royalty revenue that Curis may receive from sales of Erivedge.

Furthermore, Curis and its collaborators may experience adverse results, delays and/or failures in their drug development programs. Curis' 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 will require substantial additional capital to fund the research and development of its drug development programs. The proceeds of Curis' royalty-secured loan may not be sufficient to fund its near-term capital requirements for advancing 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 faces substantial competition from other companies developing cancer therapeutics. Unstable market and economic conditions may adversely affect Curis' financial conditions and its ability to access capital to fund the growth of its business. 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 March 31, 2013 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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