Curis Announces Erivedge(R) Receives Positive CHMP Opinion for Conditional Approval in European Union

Recommended as Treatment for Advanced Basal Cell Carcinoma
Curis Eligible for $6 Million Milestone on European Commission Approval

LEXINGTON, Mass., April 26, 2013 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), an oncology-focused company seeking to develop next generation targeted drug candidates for cancer treatment, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has recommended a conditional approval of Erivedge (vismodegib) for the treatment of adult patients with symptomatic metastatic basal cell carcinoma, or locally advanced basal cell carcinoma that is inappropriate for surgery or radiotherapy. Conditional approval would make Erivedge the first licensed treatment in Europe for patients with advanced basal cell carcinoma, a rare form of skin cancer which can be disfiguring, debilitating and even fatal.

"We are extremely pleased that the CHMP has recommended the conditional approval of Erivedge in the EU and we hope that this important medicine will soon be available to patients in Europe," said Dan Passeri, Chief Executive Officer of Curis. "We continue to be pleased by the strength of Roche's global regulatory and commercialization efforts regarding Erivedge, which we anticipate will significantly broaden patient access to Erivedge globally. Erivedge is currently under review for approval by health authorities in several countries outside of Europe, and regulatory submissions are planned in many additional countries. We view Roche's broad efforts to expand patient access to Erivedge as a testament to its commitment to this important, first-in-class molecule."

The European Commission, which has the authority to approve medicines for use in the European Union, generally delivers its final decision within three months of the CHMP recommendation. The decision will be applicable to all 27 EU member states. A European Commission conditional approval would result in Curis earning a $6 million milestone payment from Genentech, a member of the Roche Group. Roche is responsible for commercializing Erivedge in the EU.

The CHMP stated, on the basis of quality, safety and efficacy data submitted, considers there to be a favorable benefit-to-risk balance for Erivedge and therefore recommended the granting of the marketing authorization. This marketing authorization is conditional, and will require the submission of additional data from ongoing studies. The CHMP grants conditional approval to medicinal products that fulfill an unmet medical need.

About Basal Cell Carcinoma (BCC) and the Hedgehog Pathway

Basal cell carcinoma 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 basal cell carcinoma.

Roche is developing Erivedge under a collaboration agreement with Curis, Inc. 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 Mexico, Israel and South Korea.

About the ERIVANCE BCC Study

The CHMP opinion is based on findings from the pivotal ERIVANCE BCC study which enrolled 104 advanced basal cell carcinoma patients (71 had locally advanced and 33 had metastatic disease) from 31 study centers in the US, 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 basal cell carcinoma 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 Curis, Inc.

Curis is an oncology-focused company seeking to develop and commercialize next generation targeted drug candidates for cancer treatment. 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 developing its pipeline of proprietary targeted cancer drug candidates, including CUDC-427, a small molecule antagonist of IAP proteins; CUDC-907, a dual PI3K and HDAC inhibitor; and CUDC-101, an EGFR/HER2 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 statements regarding Curis' expectations regarding the timing for an approval decision in Europe, Roche's expected regulatory plans, 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, the European Commission or 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 US, Mexico or Israel. 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. 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 Annual Report on Form 10-K for the year ended December 31, 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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