Curis Announces Full Approval of Roche's Erivedge® in the European Union

LEXINGTON, Mass., Nov. 28, 2016 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of cancer, today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has granted full 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. Erivedge is also approved in the U.S. for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation. Erivedge was developed and is marketed by Roche and Genentech, a member of the Roche Group, under a collaboration agreement between Curis and Genentech.

Erivedge was originally granted ‘conditional approval' in July, 2013 in the European Union (EU) and the authorization has now been converted from ‘conditional' to ‘full approval' based on the results from the STEVIE study that included 1215 patients with advanced BCC. STEVIE (MO25616) is a single-arm, open-label, Phase II, multicenter study that was conducted by Roche to assess the safety of vismodegib in patients with locally advanced and metastatic BCC. The safety and efficacy results of the STEVIE trial were consistent with the results of the pivotal study ERIVANCE BCC (SHH4476g) that supported the initial conditional approval of the drug in the EU.

About Basal Cell Carcinoma and the Hedgehog Pathway

According to the American Cancer Society, BCC accounts for approximately 80 percent of all diagnosed skin cancers. The disease is generally considered curable if the cancer is restricted to a small area of the skin. However, in a small group of people, if the disease is left untreated or recurs in the same location after surgery or radiotherapy, it may become locally advanced and invade 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. In a small proportion of patients, BCC can metastasize, spreading to other parts of the body. Abnormal signaling in the Hedgehog pathway is implicated in more than 90 percent of BCC cases.

About Erivedge

Erivedge is designed to selectively inhibit signaling in the Hedgehog pathway by binding to a protein called Smoothened. The Hedgehog signaling pathway plays an important role in regulating proper growth and development in the early stages of life and normally becomes less active in adults. The Hedgehog signaling pathway is implicated in the development of certain types of cancer, including BCC.

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 is approved in the U.S. for the treatment of adults with metastatic basal cell carcinoma, or with locally advanced basal cell carcinoma that has recurred following surgery or who are not candidates for surgery, and who are not candidates for radiation. Erivedge is currently approved and marketed in multiple countries worldwide.

Erivedge is currently in development by Roche and Genentech in other diseases including idiopathic pulmonary fibrosis and myelofibrosis.

About the Curis-Genentech Collaboration

Under the ongoing collaboration agreement between Genentech, a wholly owned member of the Roche Group, and Curis, Erivedge (vismodegib, GDC-0449, RG3616) was discovered by Genentech and was jointly validated by the parties through a series of preclinical studies. Pursuant to this collaboration, Genentech and Roche are responsible for clinical development, and Genentech (U.S.), Roche (Ex-U.S. excluding Japan) and Chugai Pharmaceuticals (Japan) are responsible for commercialization of Erivedge. Curis receives royalties on sales of Erivedge by Genentech/Roche.

About Curis, Inc.
Curis is a biotechnology company focused on the development and commercialization of innovative and effective drug candidates for the treatment of human cancers, including its lead development candidate, CUDC-907 that is being investigated in clinical studies in patients with lymphomas and solid tumors. Curis is also engaged in a broad collaboration with Aurigene in the areas of immuno-oncology and precision oncology. As part of this collaboration, Curis has exclusive licenses to oral small molecule antagonists of the PD-1 and VISTA pathways, including PD-L1/VISTA antagonist CA-170, and oral small molecule antagonists of the PD-1 and TIM-3 pathways, including PD-L1/TIM-3 antagonist CA-327, as well as to molecules designed to inhibit the IRAK4 kinase, including CA-4948. CA-170 is currently undergoing testing in a Phase 1 trial in patients with advanced solid tumors and lymphomas. Curis is also party to a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are commercializing Erivedge® for the treatment of advanced basal cell carcinoma, and are further developing Erivedge in other diseases including idiopathic pulmonary fibrosis and myelofibrosis. For more information, visit Curis's 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 the potential advantages and benefits of small molecule checkpoint inhibitors and the Company's plans and expectations for the collaboration with Aurigene, including its plans to discover and

develop multiple first-in-class oral, small molecule checkpoint inhibitors for the treatment of patients with cancer. Forward-looking statements 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 may experience adverse results, delays and/or failures in its drug development programs and may not be able to successfully advance the development of its drug candidates in the time frames it projects, if at all. Curis's drug candidates may cause unexpected toxicities, fail to demonstrate sufficient safety and efficacy in clinical studies and/or may never achieve the requisite regulatory approvals needed for commercialization. Favorable results seen in preclinical studies and early clinical trials of Curis's drug candidates may not be replicated in later trials. There can be no guarantee that the collaboration agreement with Aurigene will continue for its full term, that Curis or Aurigene will each maintain the financial and other resources necessary to continue financing its portion of the research, development and commercialization costs, or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Regulatory authorities may determine to delay or restrict Genentech's and/or Roche's ability to continue to develop or commercialize Erivedge in BCC. Erivedge may not demonstrate sufficient or any activity to merit its further development in disease indications other than BCC. Competing drugs may be developed that are superior to Erivedge. Curis faces risks relating to its wholly-owned subsidiary's royalty-collateralized loan transaction, including the risk that it may not receive sufficient levels of royalty revenue from sales of Erivedge to satisfy the debt obligation or may otherwise lose its rights to royalties and royalty-related payments as a result of a foreclosure of the loan. Curis will require substantial additional capital to fund its business and such capital may not be available on reasonable terms, or at all. Curis faces substantial competition. Curis also faces risks relating to potential adverse decisions made by the FDA and other regulatory authorities, investigational review boards, and publication review bodies. Curis may not obtain or maintain necessary patent protection and could become involved in expensive and time-consuming patent litigation and interference proceedings. Unstable market and economic conditions and unplanned expenses may adversely affect Curis's financial conditions and its ability to access the substantial additional capital needed to fund the growth of its business. Important factors that may cause or contribute to such differences include the factors set forth under the caption "Risk Factors" in our in our most recent Form 10-K and Form 10-Q and the factors that are discussed in other filings that we periodically make with the Securities and Exchange Commission ("SEC").

In addition, any forward-looking statements represent the views of Curis only as of today and should not be relied upon as representing Curis's 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, except as may be required by law.

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