Curis Announces Collaborator Roche's Submission of Erivedge(TM) for Registration With Australian Regulatory Authority

LEXINGTON, Mass., May 7, 2012 (GLOBE NEWSWIRE) -- Curis, Inc. (Nasdaq:CRIS), a drug development company seeking to develop next generation targeted small molecule drug candidates for cancer treatment, today announced that its collaborator Roche has submitted an application for marketing registration for Erivedge™ (vismodegib) to Australia's Therapeutic Goods Administration (TGA). The application is currently under review by the TGA for the treatment of adults with advanced basal cell carcinoma (BCC) for whom surgery is inappropriate. Erivedge is a first-in-class oral medicine designed to selectively inhibit signaling in the Hedgehog pathway and is being developed by Roche and Genentech, under a collaboration agreement between Curis and Genentech, a member of the Roche Group.

Curis earned a $4 million milestone payment as a result of the submission of this application to the TGA. If Roche receives approval to commercialize Erivedge in Australia, Curis will also be entitled to receive an additional milestone payment as well as royalties on any future net sales of Erivedge in Australia.

"The Australian marketing application for Erivedge is further evidence of Roche's commitment to providing Erivedge to patients with advanced BCC around the world. In addition to Australia, Erivedge is currently under review for approval in Europe, Canada and Switzerland," said Dan Passeri, Curis President and Chief Executive Officer. "Approvals in these territories are expected to meaningfully expand patient access to Erivedge outside of the United States."

The achievement of several key Erivedge regulatory objectives by Genentech and Roche, including the launch of Erivedge in the United States, has resulted in Curis earning $28 million in milestone payments in the previous six months. Curis currently expects to receive royalty payments on U.S. sales and is eligible for milestone payments should Erivedge be approved in Europe or Australia. Curis will also receive royalty payments on net sales of Erivedge in Europe, Australia and any other country where Erivedge is approved and commercialized.

Erivedge is approved in the U.S. for the treatment of adults with BCC that has spread to other parts of the body or that has come back after surgery or that their healthcare provider decides cannot be treated with surgery or radiation.

The application to the TGA is based on clinical data from ERIVANCE BCC/SHH4476g, a pivotal Phase II study of vismodegib in patients with advanced BCC. The results were presented at the Seventh European Association of Dermato-Oncology (EADO) Congress in July 2011 as well as at the European Multidisciplinary Cancer Congress (EMCC) in September 2011.

About Basal Cell Carcinoma and the Hedgehog Pathway

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 advance 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 the Curis-Genentech Collaboration

Under the ongoing collaboration agreement between Genentech, a wholly owned member of the Roche Group, and Curis, Erivedge (vismodegib) 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 is eligible to receive cash payments upon the successful achievement of specified clinical development and regulatory approval milestones, as well as royalties assuming successful commercialization of Erivedge by Genentech and its sublicensees, which include Roche and Chugai.

Roche and Genentech are also evaluating Erivedge in a Phase II trial in people with operable forms of BCC. Furthermore, the potential of Erivedge is being evaluated by third-party investigators in a number of other disease areas. For more information, visit http://www.clinicaltrials.gov.

About Curis, Inc.

Curis is a drug development company that is committed to leveraging its innovative signaling pathway drug technologies to seek to create new targeted small molecule drug candidates for cancer. Curis is building upon its previous experiences in targeting signaling pathways, including the Hedgehog pathway, in its effort to develop proprietary targeted cancer programs. For more information, visit Curis' website at www.curis.com.

The Curis, Inc. logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=11347

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 increase in patient access and commercial potential for Erivedge if approved in territories outside of the United States and statements regarding the Company's timeline to fund its currently planned operations. 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, Genentech and Roche may not ultimately demonstrate to the satisfaction of the EMA, the TGA or other foreign regulatory agencies 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. 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. Curis also faces other important risks relating to its business, operations, financial condition and future prospects generally, that are discussed in its Annual Report on Form 10-K for the year ended December 31, 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.

CONTACT: Michael P. Gray

Chief Financial and Chief Operating Officer

Curis, Inc.

617-503-6632

mgray@curis.com
