Curis Announces Publication of Erivedge(TM) Data in the New England Journal of Medicine

LEXINGTON, Mass., June 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 two publications describing clinical data generated with Erivedge™ (vismodegib, GDC-0449) capsule were published in the current edition of *The New England Journal of Medicine (NEJM)*.

The first publication, entitled "Efficacy and Safety of Vismodegib in Advanced Basal Cell Carcinoma," reports on the results of the pivotal Phase II ERIVANCE BCC study in 104 patients with advanced basal cell carcinoma (BCC) conducted by Genentech. The second publication, entitled "Inhibiting the Hedgehog Pathway in Patients with Basal-Cell Nevus Syndrome," reports on results from an investigator-sponsored study evaluating the potential of Erivedge in 41 patients with basal cell nevus syndrome (BCNS) and surgically eligible BCCs.

Erivedge is a first-in-class oral medicine designed to selectively inhibit signaling in the Hedgehog pathway. It is also is the only FDA-approved medicine for patients with advanced BCC. There are currently no approved medicines for advanced BCC outside the United States. Erivedge is being developed by Roche and Genentech, under a collaboration agreement between Curis and Genentech, a member of the Roche Group.

"The published ERIVANCE BCC study results provide further evidence supporting the FDA approval of Erivedge for advanced BCC patients," said Dan Passeri, Curis President and Chief Executive Officer. "Efforts are also ongoing to learn more about the potential of Erivedge in patients with BCNS with surgically eligible BCCs, where recent data have demonstrated an important proof-of-concept of Erivedge efficacy in this disease. In addition, Genentech is currently conducting a Phase II clinical trial in operable BCC and an investigator-sponsored Phase II study is planned to investigate Erivedge as a pre-surgical treatment for BCC."

Mr. Passeri continued, "In addition to the ongoing clinical development efforts in BCC, Roche has filed regulatory submissions for the approval of Erivedge in advanced BCC in Europe, Australia, Canada and Switzerland, potentially expanding patient access to Erivedge."

ERIVANCE BCC Publication

The advanced BCC data reported in the NEJM publication were from a multicenter, international, two-cohort, nonrandomized Phase II study that formed the basis of the FDA approval for Erivedge. The overall response rate in the pivotal study as assessed by an independent review facility was reported as 43 percent for patients with locally advanced BCC and 30 percent for patients with metastatic BCC.

The paper's lead author, Dr. Aleksander Sekulic, presented data from six additional months of follow up on the ERIVANCE BCC study on June 3, 2012, at the Annual Meeting of the American Society for Clinical Oncology (ASCO). The updated data showed an increase in median duration of treatment from 9.8 months to 12.9 months.

The safety data were similar to those previously reported. Adverse events (AEs) in greater than 30% of patients were muscle spasms, alopecia, dysgeusia, weight decrease, fatigue, nausea, and amenorrhea in 2/6 patients. Serious AEs were reported in 32 patients (31%). No additional fatal AEs were reported since the prior data cut (n=7, 7%; none considered related to vismodegib).

BCNS Publication

The data reported in NEJM provide updated results from a Phase II, double blind, randomized, placebo-controlled, two arm, multicenter, investigator-sponsored clinical study. This study was designed to assess the safety and efficacy of 150 mg of daily oral Erivedge versus placebo and enrolled 41 BCNS patients with surgically eligible BCCs from September 2009 to January 2011.

Study results showed that all tumors responded to Erivedge treatment, with no tumors progressing and near-complete clinical remission observed in some patients. Erivedge significantly reduced the per-patient rate of new, surgically eligible BCCs below that of placebo (mean, 2 vs. 29 per year; median, 2 vs. 25 per year; $P < .001$). Erivedge also reduced the size of existing surgically-eligible BCCs from baseline when compared to placebo (mean, -65%, vs. -11% with placebo; median, -71%, vs. -21% with placebo; $p = 0.003$). Most BCCs recurred when Erivedge treatment was stopped. In an ad hoc analysis of seven patients who stopped treatment with Erivedge, 0.69 new BCCs developed per month, a rate that the authors note is considerably less than the 2.4 BCCs per month rate of the placebo group.

A Data Safety Monitoring Board recommended discontinuing the placebo arm of the trial following an interim analysis due to statistically significant differences between the two groups, in order for all of the patients enrolled in the study to receive treatment with Erivedge.

Adverse events observed were similar to what has been reported in previous clinical studies. Most adverse events were mild to moderate; altered taste, muscle cramps, hair loss and weight loss were more common with Erivedge compared to placebo. Overall, 54% of patients had discontinued medication due to side effects.

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 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 Basal Cell Nevus Syndrome (BCNS)

Basal cell nevus syndrome, also known as Gorlin syndrome, is an inherited disorder caused by a mutation of the patched gene, a member of the Hedgehog signaling pathway. One of the main features of BCNS is development of multiple BCCs, including in areas that are not exposed to sunlight.

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) 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 planned initiation of an investigator-assessed study for the pre-surgical treatment of basal cell carcinoma as well as the potential for Erivedge approval in territories outside of the United States . 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-Q for the quarter ended March 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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