Exelixis Reports Promising Interim Data From Patients With Ovarian Cancer Treated With XL184

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- 32% confirmed response rate per RECIST in patients with platinum-resistant or platinum-sensitive disease -

SOUTH SAN FRANCISCO, Calif., Nov 18, 2010 (BUSINESS WIRE) -- Exelixis, Inc. (NASDAQ:EXEL) today reported interim data from the cohort of patients with advanced epithelial ovarian cancer, primary peritoneal, or fallopian tube carcinoma treated with XL184 in an ongoing phase 2 adaptive randomized discontinuation trial (RDT). Ignace Vergote, M.D., Ph.D., Head of the Department of Obstetrics and Gynaecology and Gynaecologic Oncology at the University Hospital Leuven, Leuven, Belgium will present the data in the Molecular-Targeted Therapies-Clinical Trials poster session (Abstract #407) on Thursday, November 18th, at the 22nd EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics in Berlin, Germany.

XL184 Activity in Patients with Ovarian Cancer

As of the November 1, 2010 cut-off date, a total of 51 patients were enrolled into the ovarian cancer cohort, with 31 evaluable for response, and 41 evaluable for safety. The median number of prior systemic treatments was 2. Tumor shrinkage was observed in 30 of 37 (81%) patients with measurable metastatic lesions. Of 31 patients evaluable for response per RECIST, 10 (32%) achieved a confirmed partial response (PR). Stable disease (SD) was reported in 15 patients (48%) including 3 patients who achieved unconfirmed PRs. The overall week-12 disease control rate (DCR) was 64%.

Upon subset analysis, 5 of 17 platinum-refractory or -resistant patients (29%) evaluable for response per RECIST achieved a confirmed PR. SD was reported in 7 patients (41%) including 2 patients with unconfirmed PRs. The week-12 DCR was 59% in platinum-resistant/refractory patients. Durable responses have been observed, including 2 patients with platinum-refractory or resistant disease who remain on study for 34+ and 36+ weeks, and 3 patients with platinum-sensitive disease on study for 24, 24+, and 28+ weeks. Some patients have experienced reductions in the ovarian cancer blood marker CA125, but in general no clear concordance between CA125 changes and tumor shrinkage has been observed.

Safety data are available for 49 patients who had at least 6 weeks of follow-up. The most common Grade greater-than or equal to 3 adverse events, regardless of causality were PPE syndrome (12%), diarrhea (7%), fatigue, vomiting (each 5%), nausea, rash, abdominal pain, hypertension, and hypomagnesemia (each 2%).

"The activity of XL184 in women with both platinum-sensitive and platinum-resistant/refractory disease is unique and encouraging. The response rate and overall disease control rate of this oral agent are impressive especially in the group of patients with platinum refractory/resistant ovarian cancer, and compare favorably to other targeted and systemic agents in development," said, Dr. Vergote. "I believe these encouraging data warrant further evaluation of XL184 in ovarian cancer."

"The high response rate in patients with ovarian cancer is reflective of the broad anti-tumor activity of XL184 observed in multiple tumor types to date," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "The data from the RDT underscore the novel and differentiated clinical activity of XL184 in diverse tumor indications with predominance of either soft tissue or bone involvement."

To access the clinical data poster mentioned in this press release, please visit www.exelixis.com.

Broad Clinical Activity of XL184 - Randomized Discontinuation Trial

XL184 has demonstrated anti-tumor activity in 9 of 12 indications studied to date. In ongoing trials, compelling activity has been observed in medullary thyroid cancer, glioblastoma, and clear cell renal cancer. In the RDT, XL184 is being evaluated in nine different tumor types, with clear signals of activity in six: prostate, ovarian, hepatocellular, breast, non-small cell lung cancer and melanoma. The adaptive RDT design allowed for rapid simultaneous assessment of the activity of XL184 across nine different tumor indications. As of the November 1, 2010 cut-off date, a total of 397 patients have been enrolled into the nine disease-specific cohorts, with 273 evaluable for response, and 312 evaluable for safety. Of 273 patients evaluable for response per RECIST, 39 achieved a PR (either confirmed or unconfirmed) and 100 had SD at week 12. The week-12 DCR for the overall population was 49%, with the highest rates occurring in hepatocellular cancer (75%), castration-resistant prostate cancer (71%), ovarian cancer (64%), melanoma (45%), non-small cell lung cancer (42%) and breast cancer (42%). Of note, a breast cancer patient with evidence of bone metastasis on bone scan demonstrated evidence of resolution on bone scan accompanied by 29% reduction in tumor size. XL184 has been generally well tolerated with a consistent adverse event profile across the nine different RDT tumor types.

Conference Call and Webcast

A conference call to highlight the data from the six posters presented at the EORTC-NCI-AACR Symposium on the company's randomized discontinuation trial of XL184 will be held on November 18, at 7:30 a.m. EST / 4:30 a.m. PST. To listen to a webcast of the call, visit the Event Calendar page under Investors at www.exelixis.com.

About XL184

XL184, an inhibitor of tumor growth, metastasis and angiogenesis, simultaneously targets MET and VEGFR2, key kinases involved in the

development and progression of many cancers, including ovarian cancer. It has recently been shown in preclinical models that treatment with selective inhibitors of VEGF signaling can result in tumors that are more invasive and aggressive compared to control treatment. In preclinical studies, upregulation of MET has been shown to occur in concert with development of invasiveness after selective anti-VEGF therapy, and may constitute a mechanism of acquired or evasive resistance to agents that target VEGF signaling. Accordingly, treatment with XL184 in similar preclinical studies resulted in tumors that were less invasive and aggressive compared to control or selective anti-VEGF treatment. Therefore, XL184 has the potential for improving outcomes in a range of indications, including those where selective anti-VEGF therapy has shown minimal or no activity.

About Exelixis

Exelixis, Inc. is a development-stage biotechnology company dedicated to the discovery and development of novel small molecule therapeutics for the treatment of cancer. The company is leveraging its biological expertise and integrated research and development capabilities to generate a pipeline of development compounds with significant therapeutic and commercial potential for the treatment of cancer. Currently, Exelixis' broad product pipeline includes investigational compounds in phase 3, phase 2, and phase 1 clinical development. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, sanofi-aventis, GlaxoSmithKline, Genentech (a wholly owned member of the Roche Group), Boehringer Ingelheim, and Daiichi-Sankyo. For more information, please visit the company's web site at www.exelixis.com.

Forward-Looking Statements

This press release contains forward-looking statements by Exelixis, including, without limitation, statements related to the continued development and clinical and therapeutic potential of XL184. Words such as "encouraging," "believe," "potential" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs and expectations. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation, risks related to the potential failure of XL184 to demonstrate safety and efficacy in clinical testing; Exelixis' ability to conduct clinical trials of XL184 sufficient to achieve a positive completion; the sufficiency of Exelixis' capital and other resources; the uncertain timing and level of expenses associated with the development of XL184; the uncertainty of the FDA approval process; market competition and changes in economic and business conditions. These and other risk factors are discussed under "Risk Factors" in Exelixis' Quarterly Report for the quarter ended October 1, 2010 and Exelixis' other reports filed with the Securities and Exchange Commission. Exelixis expressly disclaims any duty, obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in Exelixis' expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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