Exelixis Reports Integrated Data From Phase II Clinical Trials of XL999 at ASCO

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CHICAGO, June 3, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Exelixis, Inc. (Nasdaq: EXEL) reported integrated data from six Phase II clinical trials of XL999 in patients with non-small cell lung cancer (NSCLC), renal cell carcinoma, metastatic colorectal cancer, recurrent ovarian cancer, acute myelogenous leukemia (AML), and multiple myeloma. Results show preliminary anti-tumor activity in patients with NSCLC and AML, as well as a cardiovascular adverse event profile consistent with previously reported data. The data were presented in a poster session on Sunday, June 3, 2007 (Abstract #3591) at the 43rd Annual Meeting of the American Society of Clinical Oncology (ASCO).

The primary objectives of each trial were to determine the response rate and to further evaluate the safety and tolerability of XL999. Secondary objectives were to assess progression-free survival, duration of response, and overall survival with XL999. Patients in the studies received a once-weekly, 4-hour intravenous infusion of XL999 dosed at 2.4 mg/kg.

"We believe this integrated report provides a clear basis for the further development of XL999 with an appropriate risk-benefit profile," said Gisela M. Schwab, MD, senior vice president and chief medical officer at Exelixis. "On the basis of these data, further clinical evaluation of XL999 is planned in patients with stage IIIB-IV NSCLC in a Phase I dose-escalation study."

Integrated results from 79 patients who participated in the Phase II trials show preliminary evidence of XL999 activity in patients with NSCLC or AML. Of nine patients in the trial with NSCLC, two had partial responses (6 months and 11+ months), and three had stable disease for at least three months. Fourteen AML patients participated in the trial, of which ten had circulating myeloblasts. Eight of these ten patients experienced at least a 50% reduction in circulating myeloblasts following administration of XL999, one of whom achieved a partial response. Three of the 14 AML patients were found to have activating mutations in FLT3, including the patient who achieved a partial response. All three of these patients experienced a greater than 98% reduction in circulating myeloblasts.

With respect to the safety of XL999, serious cardiac adverse events occurred in 11 of the 79 patients (14%). These events were associated with the dose rate of XL999 and generally were associated with the first dose. Cardiac adverse events varied in severity, ranging from asymptomatic ECG changes to cardiopulmonary failure, and usually improved with discontinuation of XL999. Nine other non-cardiac serious adverse events associated with XL999 were reported: diarrhea (1), asthenia (1), pyrexia (2), hypersensitivity (2), vena cava thrombosis (1), dehydration (1), and pulmonary hemorrhage (1).

Clinical development of XL999 was re-initiated in April 2007. This clinical trial will evaluate XL999 in patients with NSCLC who have failed at least one previous therapy. The trial will have a dose-escalation format starting at 0.4 mg/kg dosed weekly, while monitoring patients for potential cardiovascular events. Results from this Phase I clinical trial could provide Exelixis with the opportunity to move directly into a late stage clinical trial if XL999 demonstrates anti-tumor activity with an acceptable side-effect profile in this well-defined NSCLC patient population. Exelixis expects to begin enrolling patients in this trial during the summer of 2007.

About XL999

XL999 is a potent inhibitor of key receptor tyrosine kinases implicated in the development and maintenance of tumor vasculature, and in the proliferation of some tumor cells. It inhibits FGFR1, FGFR3, RET, VEGFR2, and PDGFR. The compound is also a potent inhibitor of FLT3, an important driver of leukemia cell proliferation in some patients with acute myelogenous leukemia (AML). XL999 exhibited potent activity in preclinical target-specific pharmacodynamic models, as well as efficacy models for solid tumors and for FLT3-driven leukemia.

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 and other serious diseases. The company is leveraging its fully integrated drug discovery platform to fuel the growth of its development pipeline, which is primarily focused on cancer. Currently, Exelixis' broad product pipeline includes investigational compounds in Phase II and Phase I clinical development for cancer and renal disease. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including GlaxoSmithKline, Bristol-Myers Squibb Company, Genentech, Wyeth Pharmaceuticals and Sankyo. For more information, please visit the company's web site at www.exelixis.com.

This press release contains forward-looking statements, including without limitation statements related to the safety and potential efficacy of XL999 Words such as "believes," "may," "expects," "plan," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis' current 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 lengthy, costly and uncertain process of clinical testing of XL999 and the potential failure to demonstrate safety and efficacy and the therapeutic potential of XL999. These and other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' quarterly report on Form 10-Q for the fiscal quarter ended March 30, 2007 and other filings with the Securities and Exchange Commission. Exelixis expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward- looking statements contained herein to reflect any change in the company's expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

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