Data From Phase I Trial of Exelixis' XL999 Establishing MTD Presented at Cancer Conference

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PHILADELPHIA, Nov. 17 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL) today reported data from a Phase I trial of XL999 in patients with advanced solid malignancies. Study results identified a maximum tolerated dose (MTD) of intravenously-administered XL999. When administered every two weeks, this dose demonstrated preliminary evidence of clinical activity with no cumulative toxicities. Dr. Kyriakos Papadopoulos, Clinical Investigator, Institute for Drug Development Cancer Therapy and Research Center, presented the data in a poster, titled "A Phase I dose-escalation and pharmacokinetic (PK) study of a novel spectrum-selective kinase inhibitor (SSKI), XL999, in patients with advanced solid malignancies," (Abstract C82), at the AACR-NCI- EORTC International Conference on Molecular Targets and Cancer Therapeutics.

XL999 has been administered across 6 dose levels (0.2, 0.4, 0.8, 1.6, 3.2 and 6.4 mg/kg) to 23 patients with advanced solid tumors. Both patients treated at the maximum administered dose of 6.4 mg/kg experienced hypertension and grade 3-4 elevations in liver enzyme activity (1 with fatal cardiogenic pulmonary edema). At 3.2 mg/kg, side effects observed included infusion-related hypertension, oral sensitivities, dizziness, and grade less than or equal to 2 elevation of liver enzyme activity. In general, toxicities resolved within 24 hours except for liver enzyme changes. One patient required prophylactic antihypertensive therapy prior to XL999 dosing. The 3.2 mg/kg dose has been determined to be the maximum tolerated dose (MTD).

In 22 evaluable patients who have to date been followed for greater than or equal to 8 weeks, there have been 2 partial responses (liver, thyroid), 1 minor response (28% reduction; renal cell), and 4 patients with stable disease for 3-7 months (thyroid [n=2], renal cell [n=2])

"We are very excited by these results and look forward to evaluating XL999 further in a broad targeted Phase II clinical program, which we intend to initiate very soon," said George A. Scangos, Ph.D., president and chief executive officer of Exelixis. "This is the third Phase I study of compounds generated by our internal discovery effort to be presented at this meeting. We believe that the results of these studies validate our integrated discovery and development strategy, and underscore our maturation to a development-stage biopharmaceutical company," continued Scangos.

"I am encouraged by these results, as they demonstrate that XL999 can target pathways in various cancers and was generally well tolerated at the 3.2mg/kg dose," said Dr. Papadopoulos. "Preliminary clinical activity has been observed even in this population of heavily pre-treated patients. Based on safety and PK data and the clinical signals we have seen in our study, a weekly dosing schedule is being explored, and Phase II trials to evaluate the potential of XL999 are warranted," continued Papadopoulos.

About the Trial

The primary objective of the Phase I dose escalation trial was to establish a MTD and to assess safety and tolerability of XL999. Secondary objectives included PK analyses and tumor response. Patients with advanced solid malignancies were enrolled in successive cohorts to receive XL999 intravenously as a single 4-hour infusion on day 1. If treatment was well tolerated, subjects were eligible to receive further doses of XL999 every two weeks in the absence of unacceptable toxicity or disease progression.

About XL999

XL999, a Spectrum Selective Kinase Inhibitor(TM) (SSKIs), is a potent inhibitor of key receptor tyrosine kinases (RTKs) implicated in the development and maintenance of tumor vasculature and in the proliferation of some tumor cells. It inhibits receptors for FGF, VEGF and PDGF and exhibits excellent activity in target-specific cellular functional assays. In addition, XL999 is a potent inhibitor of FLT3, an important driver of leukemia cell proliferation in patients with acute myelogenous leukemia (AML). In several preclinical models of human tumors, including breast, lung, colon and prostate cancer, XL999 demonstrated potent inhibition of tumor growth, and also caused regression of large well-established tumors.

Conference Call and Webcast

Dr. Anthony W. Tolcher, Director from the Institute for Drug Development Cancer Therapy and Research Institute will discuss preliminary Phase I trial data of XL999 at 8:00pm EST, Thursday, November 17, 2005 in the Grand Salon at the Rittenhouse Hotel, 210 West Rittenhouse Square, Philadelphia, PA 19103.

To listen to the discussion via webcast, visit the Event Calendar section under Investor on the Exelixis website at www.exelixis.com or dial 1-877-407-8033 (Int'l: 201-689-8033).

A reply of this discussion can be accessed at 1-877-660-6853. Playback account number required for playback access: 286. Playback conference identification number required for playback access: 176233.

About Exelixis

Exelixis, Inc. is a biotechnology company dedicated to the discovery and development of novel therapeutics that will potentially enhance the care and lives of patients with cancer and other serious diseases. The company is leveraging its fully integrated gene-to-drug platform to fuel the growth of its proprietary drug pipeline. Exelixis' development pipeline covers cancer and metabolism and is comprised of the following compounds: XL119 (becatecarin), for which a multinational Phase III clinical trial in bile duct tumor is ongoing and which has been exclusively licensed to Helsinn Healthcare S.A. with rights to reacquire commercial rights for North America; XL784, which is being advanced as a treatment for renal disease and is currently in a Phase I clinical trial using a newly developed capsule formulation of the compound; XL647, XL999, XL880, XL820, XL844 and XL184, anticancer compounds currently in Phase I clinical trials; and multiple compounds in preclinical development for diseases including cancer and various metabolic and cardiovascular disorders. Exelixis has established broad corporate alliances with major pharmaceutical and biotechnology companies

including GlaxoSmithKline (GSK) and Bristol-Myers Squibb Company. Pursuant to a product development and commercialization agreement between Exelixis and GSK, GSK has the option, after completion of Phase IIa clinical trials by Exelixis, to elect to develop a certain number of compounds in Exelixis' product pipeline, which may include XL784 and the cancer compounds identified in this press release (other than XL119), thus potentially triggering milestone payments and royalties from GSK and co-promotion rights by Exelixis. For more information, please visit the company's web site at www.exelixis.com.

This press release contains forward-looking statements. Words such as "believes," "anticipates," "plans," "expects," "intends," "will," "slated," "goal" 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, the potential failure of product candidates to demonstrate safety and efficacy in clinical testing; the ability of the company to complete Phase I and initiate Phase II clinical trials for XL999 at the referenced time, the ability to conduct Phase I clinical trials for XL784, XL647, XL880, XL820, XL844 and XL184 sufficient to achieve a positive completion; the uncertainty of the FDA approval process; and the therapeutic and commercial value of the company's compounds. These and other risk factors are discussed under "Risk Factors" and elsewhere in our quarterly report on Form 10-Q for the quarter ended September 30, 2005 and other filings with the Securities and Exchange Commission. The company 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.

SOURCE Exelixis, Inc.

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