Exelixis Initiates Phase II Clinical Program for XL999

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SOUTH SAN FRANCISCO, Calif., Dec 20, 2005 /PRNewswire-FirstCall via COMTEX News Network/ -- Exelixis, Inc. (Nasdaq: EXEL) today announced the initiation of a multi-trial Phase II clinical development program for XL999. The Phase II program is composed of six trials that will evaluate XL999 in a variety of cancer indications. Four solid tumor clinical trials (renal cell carcinoma, colon, ovarian and non-small cell lung cancer) are currently open for patient enrollment at several centers in the United States. Two additional trials, in acute myelogenous leukemia and multiple myeloma are expected to initiate in the near future. XL999, a Spectrum Selective Kinase Inhibitor(TM) (SSKI), is a potent small molecule inhibitor of key receptor tyrosine kinases (RTKs) implicated in the development and maintenance of tumor vasculature and in the proliferation of some tumor cells.

"We are very pleased to initiate the first Phase II clinical trial for an internally discovered compound, and we are on track to have two additional internally generated compounds in Phase II trials in the first quarter of 2006," said George A. Scangos, Ph.D., president and chief executive officer of Exelixis. "We believe the initiation of these trials reinforces our position as a product development company, and we are confident that we are pursuing the most effective development strategy to support successful later-stage clinical development efforts."

Data from the Phase I trial of XL999 in patients with advanced solid tumors were presented in November 2005 at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. Of 22 patients who had been followed for greater than or equal to 8 weeks, there were 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]). The results of the dose-escalation study also identified a dose that will be used for the Phase II clinical trials.

The Phase II trials of XL999 will evaluate the compound as a single agent, looking for responses in patients who have failed prior therapies. Some of the studies are also designed to evaluate single-agent activity of XL999 in previously untreated patients for whom conventional therapy is not appropriate. The trials will be conducted at multiple centers throughout the United States. Additionally, the company is considering combination trials of XL999 either in combination with other anti-angiogenic compounds or with cytotoxic chemotherapy.

About XL999

XL999, a Spectrum Selective Kinase Inhibitor(TM) (SSKIs), is a potent inhibitor of key RTKs implicated in the development and maintenance of tumor vasculature and in the proliferation of some tumor cells. It inhibits the FGFR, VEGFR and PDGFR RTKs and exhibited 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 some 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. Phase I studies of XL999 established a maximum tolerated dose and showed evidence of tumor responses.

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 will enter Phase II early in 2006; XL999, an anticancer compound, currently in Phase II clinical trials for a variety of solid tumors; XL647, 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.

Forward-Looking Statement

This press release contains forward-looking statements, including without limitation all statements related to Exelixis' clinical development program for XL999, the therapeutic and commercial potential of XL119, XL784, XL647, XL880, XL820, XL844 and XL184, other compounds in the Exelixis preclinical pipeline and its program in metabolic diseases. 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 to conduct the Phase II clinical trials for XL999 sufficient to achieve a positive completion;, 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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