Exelixis Initiates Phase 1 Clinical Trial for XL999

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SOUTH SAN FRANCISCO, Calif., Oct 25, 2004 /PRNewswire-FirstCall via COMTEX/ -- Exelixis, Inc. (Nasdaq: EXEL) has initiated a Phase I clinical trial to evaluate the tolerability and pharmacokinetic profile of XL999, a novel proprietary anticancer compound that targets multiple receptor tyrosine kinases (RTKs) implicated in tumor cell proliferation and angiogenesis. XL999 will be administered by intravenous infusion. The Phase 1 clinical trial is a dose-finding safety study in patients with solid tumors for whom no standard treatment is available or current treatments are ineffective.

"XL999 is the second of our internally generated anticancer compounds to begin testing in patients with various solid tumors this year," said George Scangos, PhD, CEO of Exelixis. "We are hopeful that XL999 may provide a meaningful opportunity to advance treatment for patients with various forms of cancer. Among our anticancer compounds, XL999 represents one novel and promising approach. Together with XL647, which is in a Phase 1 trial, and XL880, XL820, XL184, and XL844, all of which are slated for IND filings in 2005, we are excited about the potential therapeutic advances that our compounds may represent."

XL999 is the second Spectrum Selective Kinase Inhibitor (SSKI(TM)) that Exelixis has brought forward in clinical development. Each SSKI has a different spectrum of RTK inhibition offering the potential to achieve efficacy through inhibition of multiple RTKs based on their established or potential involvement in cancer. In pre-clinical testing, XL999 inhibited KDR, FGFR1, PDGFR-beta and FLT3 with high potency. In animal models, XL999 exhibited a broad spectrum of antitumor activity across several tumor types and shrinkage of large, well-established xenografts. The clinical development program for XL999 will determine its safety profile, optimal dose and regimen, and efficacy against specific tumor types.

About Exelixis

Exelixis, Inc. is a leading genomics-based drug discovery company dedicated to the discovery and development of novel therapeutics across various therapy areas. The company is leveraging its fully integrated gene-to-drug platform to fuel the growth of its proprietary drug pipeline. Exelixis' development pipeline currently covers cancer and metabolism and is comprised of the following compounds: XL119 (becatecarin), for which a Phase 3 clinical trial has been initiated in patients with bile duct tumors; XL784, initially an anticancer compound, which has completed a Phase 1 clinical trial and is currently being developed as a treatment for renal disease; XL647 and XL999, which are currently in Phase 1 clinical trials; XL880, XL820, XL844 and XL184, anticancer compounds that are potential IND candidates; and multiple compounds in preclinical development for diseases including cancer, lipid disorders, hyperlipidemia and congestive heart failure. 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 2a clinical trials, to elect to develop a certain number of compounds in Exelixis' product pipeline, which may include the cancer compounds identified in this press release (other than the company's cancer compound XL119), thus potentially triggering milestone payments and royalties from GSK and co-promotion rights by Exelixis. The company has also established agricultural research collaborations with Bayer CropScience and Dow AgroSciences. Other partners include Merck & Co., Inc., Schering-Plough Research Institute, Inc., Cytokinetics, Inc., Elan Pharmaceuticals, Inc. and Scios Inc. For more information, please visit the company's web site at www.exelixis.com.

This press release contains forward-looking statements, including without limitation all statements related to Exelixis' Phase I clinical program for XL999, the therapeutic and commercial potential of XL119, 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," "intend," "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 ability of the company to successfully conduct the clinical trials for XL119, XL647 and XL999; the ability of the company to advance additional preclinical compounds into clinical development; 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 June 30, 2004 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.

SOURCE Exelixis, Inc.

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