Exelixis Files IND Application for Anticancer Compound XL999

June 29, 2004

SOUTH SAN FRANCISCO, Calif., June 29 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL) has submitted an investigational new drug application (IND) to the U.S. Food and Drug Administration (FDA) for XL999, a proprietary novel anticancer compound. Preclinical studies with XL999 have demonstrated potent inhibition in vivo against multiple receptor tyrosine kinases (RTKs) that are implicated in tumor angiogenesis, or the development and maintenance of tumor vasculature. Pending clearance by the FDA, the company intends to initiate a Phase 1 clinical trial.

XL999 is one of several Spectrum Selective Kinase Inhibitors(TM) (SSKI) in Exelixis' product pipeline. Each SSKI has a different RTK inhibition spectrum, and each has the potential to achieve efficacy through simultaneous inhibition of multiple RTKs. Preclinical studies have shown that XL999 simultaneously inhibits the FGFR, VEGFR, PDGFR and Flt3 RTKs with high levels of potency and demonstrates excellent activity in target-specific cellular functional assays. XL999 has demonstrated potent anti-tumor activity in a variety of preclinical models of solid tumors as well as a Flt3-driven model of leukemia.

"This IND application is the second we have filed this year, which is the direct result of the productivity of our R&D groups," said George A. Scangos, Ph.D., president and chief executive officer. "Together with XL119, which recently began a pivotal Phase 3 study, XL784, which has successfully completed a Phase 1 study, XL647, which has begun a Phase 1 study, and a rich portfolio of pre-clinical development compounds, XL999 is part of a growing, high-quality pipeline of compounds that we intend to advance rapidly into and through clinical trials. Our goal is to leverage our significant expertise in biology, drug discovery, and development to generate a diverse portfolio of anti-cancer compounds with substantial therapeutic and commercial potential. This IND application is one more sign that we are executing on our vision of becoming a major cancer therapeutics company."

The Phase 1 clinical trial of XL999 will be an open-label, dose escalation study conducted in cancer patients. The study is designed to measure the safety, tolerability, pharmacokinetics, pharmacodynamics and biological activity of XL999 following a single intravenous administration. The study will be conducted at a major medical center in the United States.

Pursuant to a product development and commercialization agreement between Exelixis and GlaxoSmithKline (GSK), GSK has the option, after completion of Phase 2a clinical trials, to elect to develop a certain number of the cancer compounds in Exelixis' product pipeline (other than the company's cancer compound XL119), which may include XL999, thus potentially triggering milestone payments and royalties from GSK and co-promotion rights by Exelixis.

Exelixis, Inc. is a leading genomics-based drug discovery company dedicated to the discovery and development of novel therapeutics. The company is leveraging its fully integrated gene-to-drug platform to fuel the growth of its proprietary drug pipeline. Exelixis' development pipeline includes: XL119 (becatecarin), for which a Phase 3 clinical trial has been initiated in patients with bile duct tumors; XL784, which has completed a Phase 1 clinical trial; XL647, which is currently in a Phase 1 clinical trial; XL999 for which an IND has been filed; XL844, XL820 and XL880, anticancer compounds that are potential IND candidates; and multiple compounds in preclinical development. Exelixis has established broad corporate alliances with major pharmaceutical and biotechnology companies, including GSK and Bristol-Myers Squibb Company. The company has also established agricultural research collaborations with Bayer CropScience, Dow AgroSciences and Renessen LLC. 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 plans to advance XL999 into clinical development, and the therapeutic and commercial potential of XL647, XL119, XL999, XL844, XL820, XL880 and other compounds in Exelixis preclinical pipeline. 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, risks related to the ability of the company to successfully advance and develop XL999 and other preclinical compounds, the ability of the company to successfully conduct the Phase 1 clinical trial of XL647 and the Phase 3 clinical trial of XL119, and to initiate the Phase 1 clinical trial of XL999 later in 2004, and the uncertainty of the FDA approval process with respect to and commercial value of these and other compounds in the company's pipeline. These and other risk factors are discussed under "Risk Factors" and elsewhere in our quarterly report on Form 10-Q for the quarter ended March 31, 2004 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.

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