



Exelixis Initiates Phase I Clinical Trial for Anticancer Compound XL820

July 25, 2005

SOUTH SAN FRANCISCO, Calif., July 25 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL) has initiated a Phase I clinical trial to evaluate the safety, tolerability and pharmacokinetic profile of XL820, a novel, orally administered, small molecule anticancer compound. XL820 is a Spectrum Selective Kinase Inhibitor (SSKITM) that simultaneously inhibits the receptor tyrosine kinases (RTKs) VEGF, KIT and PDGF all of which are clinically validated targets implicated in a variety of human cancers.

The Phase I clinical trial is designed as an open-label, single and repeat dose-escalation study and will be conducted in patients with solid tumors for whom there are no available therapies known to prolong survival. The trial will be conducted at two highly regarded centers, one being the CTRC (Cancer Therapy and Research Center) Institute for Drug Development (IDD) in San Antonio, Texas.

"This is the second of four compounds we expect to enter into Phase I clinical trials this year. I am incredibly proud of the diligent work of our clinical development team. Their extraordinary ability to execute is essential to the success of Exelixis as we move towards reaching the goal of providing novel therapies to cancer patients," said George A. Scangos, Ph.D., president and chief executive officer of Exelixis.

XL820 exhibits dose-dependent growth inhibition in models of breast carcinoma, gliomas and leukemia. In an animal model of more advanced malignancy, significant tumor regression was seen. In non-clinical studies, XL820 has shown good oral bioavailability and sustained inhibition of target RTKs in vivo following a single oral dose.

Exelixis' Oncology Program

Exelixis' oncology program is focused on the development of compounds that are optimized to specifically target kinases and other molecules implicated in tumor cell proliferation and angiogenesis, thereby providing the potential for more potent therapeutic effects. The company currently has four anticancer compounds in active Phase I trials (XL647, XL999, XL880 and XL820) and anticipates initiating two additional Phase I studies in the second half of 2005 (XL844 and XL184). Exelixis anticipates that it will complete the Phase I trials for XL647 and XL999 in the second half of 2005 and plans to initiate broad Phase II trial programs for these compounds as soon as practicable. Exelixis is continuing to expand its oncology program by advancing novel, high-quality compounds into clinical development. All six programs have the potential to be first-in-class or best-in-class therapies and were generated by Exelixis' internal drug discovery efforts.

About Exelixis

Exelixis, Inc. is a leading genomics-based drug discovery company dedicated to the discovery and development of novel therapeutics across various disease areas. 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 tumors is ongoing and which has been exclusively licensed to Helsinn Healthcare SA with rights to reacquire commercial rights for North America; XL784, initially an anticancer compound, which completed a Phase I clinical trial and is being advanced as a treatment for renal disease; XL647, XL999, XL880 and XL820, anticancer compounds currently in Phase I clinical trials; XL844 and XL184, anticancer compounds for which INDs have been filed; 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 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, including without limitation all statements related to Exelixis' clinical development program for XL820, the therapeutic and commercial potential of XL119, XL784, XL647, XL880, XL999, 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 ability to successfully conduct the clinical trials for XL119, XL647, XL999, XL880, XL820, XL844 and XL184; 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 March 31, 2005 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.

NOTE: Exelixis and the Exelixis logo are registered U.S. trademarks. Spectrum Selective Kinase Inhibitor is a trademark of Exelixis, Inc.

SOURCE Exelixis, Inc.

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07/25/2005

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CO: Exelixis, Inc.
ST: California
IN: MTC
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6806 07/25/2005 06:00 EDT <http://www.prnewswire.com>