Exelixis Files IND Application for Novel Anticancer Compound XL844

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SOUTH SAN FRANCISCO, Calif., May 2, 2005 /PRNewswire-FirstCall via COMTEX/ -- Exelixis, Inc. (Nasdaq: EXEL) has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) for XL844, the sixth compound to advance in clinical development from the company's internal discovery program within two years. The company believes that XL844 is the first potent, selective inhibitor of the checkpoint kinase pathway to progress to this stage of development. In addition to its therapeutic potential as a single agent, XL844 increased the effectiveness of other anticancer agents in animal models. Pending FDA clearance, Exelixis intends to initiate a Phase I clinical trial.

"I am pleased we were able to file the IND for XL844 only one week after filing the IND for XL820. This accomplishment further highlights the productivity of our discovery, development and regulatory groups. We are excited about the potential of these compounds to enhance the effectiveness of therapy for cancer patients and we are looking forward to moving both XL820 and XL844 aggressively through clinical development," said George A. Scangos, Ph.D., president and chief executive officer of Exelixis.

XL844 is a potent, selective inhibitor of Chk 1 and 2, protein kinases that induce cell cycle arrest in response to a variety of DNA damaging agents. Its spectrum of activity includes inhibition of two vascular endothelial growth factor receptors (VEGFR2 and VEGFR3) known to be involved in tumor angiogenesis. In preclinical studies, XL844 has demonstrated significant potency in biochemical and cellular assays, oral bioavailability and an attractive pharmacokinetic profile. XL844 increases the efficacy of an array of chemotherapeutic agents in cellular and tumor models without an associated increase in systemic toxicity.

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 three cancer compounds in active Phase I trials (XL647, XL999 and XL880) and anticipates to initiate two additional Phase I studies over the course of the next few weeks (XL820 and XL844). XL784, which was initially developed as a cancer compound, is now in development for renal disease. All six compounds were generated by Exelixis' internal drug discovery efforts. Exelixis anticipates that it will complete the Phase I trials for XL647 and XL999 in the second half of 2005 and to initiate broad Phase II trial programs for these compounds as soon as practicable thereafter. The Phase I trial for XL880 was initiated in March and is actively enrolling patients. Exelixis is continuing to expand its oncology program by advancing additional diverse, high-quality compounds into clinical development, including XL184 for which an IND filing is anticipated in the first half of 2005.

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 has been initiated in patients with bile duct tumors; XL784, initially an anticancer compound, which completed a Phase I clinical trial and is being advanced as a treatment for renal disease; XL647, XL999 and XL880, anticancer compounds currently in Phase I clinical trials; XL820 and XL844 for which INDs have been filed; XL184 a potential IND candidate for the treatment of cancer; 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 XL844, 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 of the company to successfully conduct the clinical trials for XL119, XL647, XL999, XL880, XL820 and XL844; 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 annual report on Form 10-K for the year ended December 31, 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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