Exelixis Files IND Application for Anticancer Compound XL184

June 14, 2005

SOUTH SAN FRANCISCO, Calif., June 14 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL) has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration (FDA) for XL184, the seventh compound to advance into clinical development from the company's internal discovery program within two years. In preclinical studies, XL184 has shown potent inhibition of the hepatocyte growth factor receptor (Met) and vascular endothelial growth factor receptor 2 (VEGFR2 [KDR]) receptor tyrosine kinases (RTKs), proteins, which are believed to play synergistic roles in promoting tumor growth and angiogenesis. Additionally, XL184 has exhibited potent inhibition of other important RTKs that have been implicated in various forms of cancer including mast/stem cell growth factor (KIT), FMS-like tyrosine kinase 3 (Flt3) and tyrosine-protein kinase receptor (Tie-2). In preclinical efficacy studies, XL184 prevented tumor growth and induced the regression of large tumors in a broad range of human tumor xenograft models including breast cancer, lung cancer and glioma. In laboratory studies, XL184 has demonstrated significant oral bioavailability and excellent pharmacokinetic properties. Pending FDA clearance, Exelixis intends to initiate a Phase I clinical trial.

"The XL184 IND is the third IND that we have filed this year. XL184, together with XL844, and XL820 is expected to enter Phase I trials in the near future. In addition, active Phase I trials are ongoing for XL880, XL647, and XL999, and XL784 will re-enter clinical development for renal failure later this year. If we project forward to year-end 2005, we anticipate having rights to one compound (XL119) in Phase III, two compounds (XL647 and XL999) in Phase II, another two compounds (XL880, XL784) close to the Phase I/II transition, and three compounds (XL844, XL820, XL184) in Phase I. All of these compounds, except for XL119, are derived from our internal R&D. I am extremely proud of the remarkable productivity at Exelixis and am confident in our ability to rapidly and intelligently advance and fund our robust portfolio of diverse, high-quality compounds through clinical development. All of these exciting compounds have the potential to be first-in-class or best-in-class treatments that we hope will fulfill our ultimate goal of providing benefit to patients in need," said George A. Scangos, Ph.D., president and chief executive officer of Exelixis.

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 anticancer compounds in active Phase I trials (XL647, XL999 and XL880) and anticipates initiating two additional Phase I studies in the second half of 2005 (XL820 and XL844). 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. Exelixis is continuing to expand its oncology program by advancing additional diverse, high-quality compounds into clinical development, including XL184 for which an IND has been filed. All six compounds 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 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 and XL880, anticancer compounds currently in Phase I clinical trials; XL820, 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 XL184, 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, 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 annual 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.

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