



Exelixis Files IND Application for Anticancer Agent XL647

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SOUTH SAN FRANCISCO, Calif., February 19 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL) has submitted an investigational new drug (IND) application for XL647, a proprietary novel anticancer compound. XL647 demonstrates potent inhibition in vitro against multiple receptor tyrosine kinases (RTKs) that are implicated in tumor proliferation and vascularization (angiogenesis). Pending clearance by the U.S. Food & Drug Administration (FDA), the company intends to initiate a Phase 1 clinical trial in the second quarter of 2004.

XL647 is the first of several Spectrum Selective Kinase Inhibitors(TM) (SSKI) that Exelixis intends to advance into clinical development. Each SSKI has a different RTK inhibition spectrum, and each has the potential to achieve efficacy through simultaneous inhibition of multiple RTKs. XL647 simultaneously inhibits the EGFR, HER2, VEGFR and EphB4 RTKs with high potency and demonstrates excellent activity in target-specific cellular functional assays. XL647 has good oral bioavailability in preclinical models and shows sustained inhibition of target RTKs in vivo following a single oral dose. In preclinical models of major tumor types, including human breast, lung, colon and prostate cancer, XL647 demonstrates potent inhibition of tumor growth and has been shown to cause tumor regression. Consistent with its spectrum of activity, analysis of tumors from XL647-treated animals shows significant decreases in both tumor vascularity and tumor cell proliferation and an increase in tumor cell death.

"We believe that Exelixis is generating a therapeutically and commercially valuable anticancer pipeline," said George A. Scangos, Ph.D., president and chief executive officer. "XL647 is the first of what we believe is a very exciting portfolio of novel and highly potent anticancer compounds advancing toward clinical development whose activity is a direct result of selectively inhibiting a spectrum of target RTK proteins, not just a single target. We are equally enthusiastic about XL999, XL844 and other preclinical compounds in our growing pipeline, and we anticipate filing additional IND applications and initiating multiple clinical development programs during the course of this year and in 2005."

The Phase 1 clinical trial of XL647 will be an open-label, single and repeat dose escalation study conducted in subjects with solid tumors for whom there is no approved therapy. The study is designed to measure the safety, tolerability, pharmacokinetics and biological activity of XL647 following oral administration. The study will be conducted at two major medical centers in the U.S.

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 which is anticipated to enter a Phase 3 clinical trial as a potential treatment for bile duct tumors; XL784, an anticancer compound that has completed a Phase 1 clinical trial; XL647, for which an IND application has been submitted; XL999 and XL844, 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 GlaxoSmithKline and Bristol-Myers Squibb Company. After completion of Phase 2a clinical trials, GlaxoSmithKline has the right to elect to develop a certain number of the cancer compounds identified in this release, other than XL119, thus potentially triggering milestone payments and royalties from GlaxoSmithKline and co-promotion by Exelixis. 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 XL647 into clinical development, as well as plans to commence a Phase 3 clinical trial of XL119 and the therapeutic and commercial potential of XL647, XL119, XL999, XL844 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 XL647 and other preclinical compounds, the ability of the company to initiate the planned Phase 3 clinical trial of XL119 in the second quarter of 2004 and the uncertainty of the FDA approval process with respect to and commercial value of these 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 September 30, 2003 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.

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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