



Exelixis Initiates Phase 3 Clinical Trial of XL119 in Bile Duct Cancer

June 23, 2004

SOUTH SAN FRANCISCO, Calif., June 23 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL) announced the initiation of the Phase 3 clinical trial of XL119 (becatecarin) as a potential treatment for patients with bile duct cancer. The Phase 3 trial will include approximately 60 centers in the United States, Canada and Europe and is designed to enroll up to 600 patients with inoperable bile duct tumors. The primary endpoint of the trial is survival, and the two-arm trial is designed to compare patients treated with XL119 to patients treated with 5-FU/leucovorin.

"The initiation of the Phase 3 trial of XL119 in bile duct cancer is an important milestone for Exelixis," said George A. Scangos, Ph.D., president and chief executive officer. "For the patients and families who are affected by bile duct cancer, and for whom there are no approved therapies, we are hopeful that XL119 may provide some benefit. We are gratified by the enthusiasm and commitment of clinical investigators in North America and in Europe to this clinical program. We intend to work closely with Covance, our drug development services coordinator, to conduct the Phase 3 clinical trial in a high quality and expeditious manner. We are also appreciative of the National Cancer Institute's interest in continuing to explore the utility of XL119 in other indications, as encouraging results from these independent exploratory trials could suggest further development activities that Exelixis could undertake for the compound."

Data presented at the 2003 annual meeting of the American Society of Clinical Oncology (ASCO) from the Phase 2 clinical trial of XL119 showed that patients with bile duct tumors (gall bladder tumors and cholangiocarcinomas) treated with XL119 showed encouraging results relative to overall survival and progression free survival (alive without progressive disease, i.e., patients with partial response or stable disease). The safety profile of the compound was manageable and was consistent with that previously observed in Phase 1 and 2 studies. At this meeting, data were also presented showing a survival benefit in patients with non-small cell lung cancer. Data presented at the 2004 ASCO meeting showed additional encouraging results from a Phase 2 trial in patients with refractory breast cancer. Taken together, these findings suggest that XL119 is an active anticancer agent that warrants further clinical study to assess its therapeutic benefit.

In March 2004, Exelixis was granted orphan drug designation for XL119 in bile duct cancer. Orphan drug status is granted to treatments for diseases that affect fewer than 200,000 people in the U.S. and provides the benefits of extended market exclusivity for seven years, tax credits of up to 50% of the qualified clinical trial expenses and a waiver of FDA user fees. The company may also consider applying for European orphan drug designation for XL119 following the commencement of the Phase 3 clinical trial in Europe. Based on market research, Exelixis estimates that the annual incidence of bile duct tumors in currently addressable markets is approximately 30,000 patients.

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 has entered a Phase 3 clinical trial as a potential treatment for bile duct tumors; XL784, a compound that has completed a Phase 1 clinical trial; XL647, an anticancer compound that has entered a Phase 1 clinical trial; XL999, XL844, XL820 and XL880, anticancer compounds that are potential IND candidates; and multiple other compounds in preclinical development. Exelixis has established broad corporate alliances with major pharmaceutical and biotechnology companies, including GlaxoSmithKline and Bristol-Myers Squibb Company. Under the terms of our research and development collaboration with GlaxoSmithKline, established in October 2002, after completion of proof-of-concept clinical trials, GlaxoSmithKline has the right to elect to develop a limited number of the compounds in our clinical and preclinical pipeline, other than XL119, thus potentially triggering milestone payments and royalties from GlaxoSmithKline. Exelixis has co-promotion rights with GlaxoSmithKline for compounds commercialized under the collaboration. 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 the expected structure of the Phase 3 clinical trial of XL119 and the therapeutic and commercial potential of XL119, XL784, XL647, XL999, XL844, XL820 and 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 complete the planned Phase 3 clinical trial of XL119; the uncertainty of the clinical trials process and whether the company's product candidates, including XL119, will demonstrate safety and efficacy; and uncertainty regarding the ability of the company to enroll patients in a timely manner. 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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Spectrum selective kinase inhibitor is a trademark of Exelixis, Inc.

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06/23/2004

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3544 06/23/2004 06:00 EDT <http://www.prnewswire.com>