



## Exelixis Files IND for First Proprietary Anticancer Compound

March 31, 2003

SOUTH SAN FRANCISCO, Calif., March 31 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL) has submitted its first investigational new drug (IND) application to the U.S. Food & Drug Administration for its proprietary small molecule anticancer compound XL784. The target against which XL784 is directed is a cell surface protease involved in cleavage of growth factors that promote cell growth and differentiation. The target was originally discovered in Exelixis' anti-angiogenesis research program, and shows both anti-angiogenic and anti-proliferative effects. In preclinical studies, XL784 is orally bioavailable, and has shown good potency, pharmacologic activity, and a safety profile appropriate to support Phase 1 studies. The company's clinical plans include initiating Phase 1 first-in-man studies, to be conducted in healthy volunteers, while continuing to explore the therapeutic utility of the compound in various animal models of disease, including cardiovascular disease.

"Filing the IND for XL784 is a significant achievement for our company, and the credit for this success goes to the dedicated people in our development group and throughout our R&D organization," said George A. Scangos, Ph.D., president and chief executive officer. "The filing of the IND is the beginning of a development process that we intend to manage prudently. We will learn more about the safety, pharmacokinetic and pharmacodynamic merits of this experimental anticancer compound in Phase I studies and, in parallel, continue to explore other indications in which the compound may have therapeutic application. XL784 is among the first generation of interesting, novel targeted therapies that are emerging from our discovery platform. Our goal is to build a substantial pharmaceutical portfolio by advancing additional promising preclinical programs, filing a series of INDs, and fueling the growth of a diverse clinical pipeline."

Pending FDA clearance of the IND, Exelixis intends to initiate the Phase 1 program by the late spring 2003. The trial will be conducted at a single center and is designed as a dose escalation study to measure the safety, pharmacokinetics, and biological activity of XL784 following oral administration. Based on preclinical studies, the compound appears appropriate for testing in healthy volunteers and, to date, has shown none of the toxicities associated with traditional anticancer compounds that act through a cytotoxic mechanism. A third-party manufacturer is supplying the drug product to be used in the clinical trial.

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 has established broad corporate alliances with major pharmaceutical and biotechnology companies, including GlaxoSmithKline, Bristol-Myers Squibb, and Protein Design Labs. The company has also established agricultural research collaborations with Bayer CropScience, Dow Agrosciences and Renessen. Other partners include Merck, Schering-Plough Research Institute, Cytokinetics, Elan and Scios. For more information, please visit the company's web site at [www.exelixis.com](http://www.exelixis.com).

The forward looking statements contained in this press release involve risks and uncertainties that may affect our research and development efforts, as more fully discussed in the "Risk Factors" section of our filing with the U.S. Securities and Exchange Commission. These risks and uncertainties include, but are not limited to, the ability of the Company to initiate the Phase 1 clinical study in a rapid and timely manner consistent with a late spring 2003 timeline; the ability of the Company to demonstrate the safety and efficacy of XL784; the commercial value of XL784; and the ability of the Company to successfully develop XL784.

Exelixis and the Exelixis logo are registered U.S. trademarks.

SOURCE Exelixis, Inc.

-0-

03/31/2003

/CONTACT: Jane M. Green, Ph.D., VP, Corporate Communications, of Exelixis, Inc., +1-650-837-7579 or [jmgreen@exelixis.com](mailto:jmgreen@exelixis.com)/

/Web site: <http://www.exelixis.com> /

(EXEL)

CO: Exelixis, Inc.

ST: California

IN: BIO MTC HEA

SU:

JO

-- SFM018A --

0278 03/31/2003 06:00 EST <http://www.prnewswire.com>