Exelixis Files IND Application for XL765

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-Third compound to target PI3K signaling pathway inhibits PI3K and mTOR-

SOUTH SAN FRANCISCO, Calif., April 25, 2007 /PRNewswire-FirstCall via COMTEX News Network/ -- Exelixis, Inc. (Nasdaq: EXEL) today announced that it has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration for XL765. The compound is a potent and selective orally available small molecule shown in preclinical studies to inhibit the activity of phosphoinositide-3 kinase (PI3K), which is frequently activated in tumors and promotes cell growth, survival and resistance to chemotherapy and radiotherapy. XL765 also inhibits mammalian target of rapamycin (mTOR), which also is activated frequently in human tumors and plays a central role in tumor cell growth.

"In less than four months, we have filed three INDs for novel anticancer compounds that target the PI3K pathway," said Gisela M. Schwab, MD, senior vice president and chief medical officer at Exelixis. "XL765 is a balanced, dual inhibitor of PI3K and mTOR, kinases which play a central role in promoting tumor cell growth and survival. In preclinical studies, XL765 has slowed the growth or caused regression of tumors in a variety of cancer models. We believe XL765 is another example of our ability to generate insight into critical cancer-related pathways and to translate that understanding into potentially first-in-class compounds."

This is the 13th IND that Exelixis has filed for an internally developed compound in just over three years.

About XL765

XL765 is an orally available small molecule that has been shown in preclinical studies to selectively inhibit the activity of phosphoinositide-3 kinase (PI3K) and mammalian target of rapamycin (mTOR). Activation of PI3K is a frequent event in human tumors, promoting tumor cell growth, survival, and resistance to chemotherapy and radiotherapy. mTOR is also frequently activated in human tumors and plays a central role in tumor cell growth. mTOR can be activated via upregulation of PI3K, or via PI3K-independent mechanisms. Inactivation of PI3K has been shown to inhibit growth and induce apoptosis (programmed cell death) in tumor cells, whereas inactivation of mTOR has been shown to inhibit the growth of tumor cells. In preclinical studies, XL765 slowed tumor growth or caused tumor shrinkage in multiple preclinical cancer models, including breast, lung, ovarian, and prostate cancers, and gliomas. XL765 has also been shown to enhance the anti-tumor effects of several chemotherapeutic agents in preclinical cancer models.

About Exelixis

Exelixis, Inc. is a development-stage biotechnology company dedicated to the discovery and development of novel small molecule therapeutics for the treatment of cancer and other serious diseases. The company is leveraging its fully integrated drug discovery platform to fuel the growth of its development pipeline, which is primarily focused on cancer. Currently, Exelixis' broad product pipeline includes investigational compounds in Phase II and Phase I clinical development for cancer and renal disease. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including GlaxoSmithKline, Bristol-Myers Squibb Company, Genentech, Wyeth Pharmaceuticals and Sankyo. For more information, please visit the company's web site at www.exelixis.com.

This press release contains forward-looking statements, including without limitation statements related to the potential efficacy of XL765. Words such as "believes," "may," "potential," "plans," "expects," "intends," "will," "suggests" 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 potential failure of product candidates to demonstrate safety and efficacy in clinical testing; the ability to complete and initiate trials at the referenced times; the ability to conduct clinical trials sufficient to achieve a positive completion; 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 Exelixis' annual report on Form 10-K for the year ended December 29, 2006 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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