# Exelixis Files IND Application for XL418

January 30, 2007

SOUTH SAN FRANCISCO, Calif., Jan. 30 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL) announced today that it has submitted an investigational new drug (IND) application to the U.S. Food and Drug Administration for XL418, a novel anticancer compound. XL418 is an inhibitor of protein kinase B (PKB or AKT) and S6 Kinase (S6K), key components of the phosphoinosotide-3 kinase (PI3K) signaling pathway. Activation of these kinases is a frequent event in human tumors, promoting cell growth, survival and resistance to chemotherapy and radiotherapy.

"One of our drug development strategies is to systematically target key nodes in signaling pathways that are frequently deregulated in human tumors. An important component of this strategy is our focus on signaling downstream of PI3K," said Gisela M. Schwab, M.D., senior vice president and chief medical officer at Exelixis. "Despite the pivotal nature of PI3K signaling in multiple aspects of tumor cell growth, survival, and resistance, this pathway is inadequately addressed by current therapies. Preclinical studies demonstrate that XL418 potently inhibits the activity of AKT and S6K in preclinical models, reducing tumor growth and enhancing the effects of other targeted therapies. These findings suggest that XL418 may have broad utility both as a single agent and in combination with other therapies. To our knowledge, XL418 is the first dual inhibitor of AKT and S6K to enter clinical development."

With this IND filing, Exelixis now has 11 compounds in or about to enter clinical development, including four compounds in Phase II clinical programs. The company expects to file at least three other INDs for additional compounds in 2007.

About XL418

XL418 is a small molecule that inhibits the activity of protein kinase B (PKB or AKT) and S6 Kinase (S6K), which act downstream of phosphoinosotide-3 kinase (PI3K). Activation of these kinases is a frequent event in human tumors, promoting cell growth, survival, and resistance to chemotherapy and radiotherapy. Inactivation of the pathway through inhibition of AKT is expected to induce apoptosis (programmed cell death) in tumor cells. AKT inhibitors may also sensitize tumor cells to a wide range of chemotherapy. In preclinical studies, XL418 slowed tumor growth in multiple cancer models, including breast and lung adenocarcinomas. XL418 also has been shown to enhance apoptosis in combination with XL647, an inhibitor of multiple receptor tyrosine kinases including EGFR, HER2, and VEGFR, in preclinical tumor 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 XL418. Words such as "believes," "designed," "may," "potential," "anticipates," "plans," "expects," "intends," "will," "suggests," "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 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 our quarterly report on Form 10-Q for the quarter ended September 30, 2006 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.

SOURCE Exelixis, Inc.
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