



Exelixis Files IND Application for XL518

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SOUTH SAN FRANCISCO, Calif., Dec. 20 /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 XL518, a novel anticancer compound. XL518 is a potent and specific inhibitor of MEK, a key component of the RAS/RAF/MEK/ERK pathway. Inappropriate activation of this pathway is a prevalent feature of tumor cells and drives tumor growth and survival. Activation of the pathway occurs as a result of mutations in RAS in approximately 30% of all human tumors, and in B-RAF in 60 percent of melanomas.

"XL518 is the second Exelixis compound designed to inhibit the RAS/RAF/MEK/ERK pathway with high potency and specificity, and the first to specifically target MEK," said George A. Scangos, president and chief executive officer of Exelixis. "A key part of our drug discovery and development strategy is to focus on blocking signaling nodes in pathways that are mutationally activated in human cancers. This targeted approach has the potential to be broadly effective, and complements our portfolio of spectrum-selective receptor tyrosine kinase inhibitors that are currently advancing in the clinic."

About XL518

XL518 is a novel small molecule drug designed to inhibit the activity of MEK, a key component of the RAS/RAF/MEK/ERK signaling pathway. This pathway is frequently activated in human tumors, and is required for transmission of growth-promoting signals from numerous receptor tyrosine kinases. Preclinical studies have demonstrated that XL518 is a potent and specific inhibitor of MEK, with highly optimized pharmacokinetic and pharmacodynamic properties. XL518 has excellent oral bioavailability in multiple species, and induces substantial and durable inhibition of ERK phosphorylation in xenograft tumor models. Administration of XL518 causes tumor regression in multiple xenograft models with mutationally-activated B-RAF or RAS.

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 XL518. 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. 12/20/2006

CONTACT: investors,

Charles Butler, Director, Corporate Communications, +1-650-837-7277, or cbutler@exelixis.com,

or media, Soleil Maxwell Harrison, Senior Manager, Corporate Communications, +1-650-837-7012, or sharrison@exelixis.com, both of Exelixis, Inc.

Web site: <http://www.exelixis.com> / (EXEL)