Exelixis Reports Top-Line Results of the Phase 2 Trial of XL784 in Patients With Proteinuria Associated With Diabetic Nephropathy

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- Data to be presented November 2 at the American Society of Nephrology Meeting -

SOUTH SAN FRANCISCO, Calif., Oct. 16 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL) announced that a recently completed phase 2 trial of XL784 did not meet its primary endpoint of reducing proteinuria compared with placebo in patients with proteinuria associated with diabetic nephropathy. Exelixis is continuing to analyze the data to assess whether further evaluation of the compound is warranted.

Proteinuria, the presence of excess protein in the urine, is an indicator of renal disease. Albumin excretion is a risk factor for kidney failure, stroke and cardiovascular and all-cause mortality, particularly in patients with diabetes and/or hypertension. Nephropathy (kidney disease) is a common problem in diabetic patients, often leading to the need for hemodialysis or kidney transplant. XL784 is a potent small molecule inhibitor of MMP2 and ADAM10, metalloprotease enzymes that may play a role in renal fibrosis and impairment.

"We obviously are disappointed that this trial did not meet its primary endpoint," said George A. Scangos, Ph.D., president and chief executive officer of Exelixis. "However, the compound was well tolerated, and we are continuing to analyze the data to determine if the compound may have utility in the treatment of diabetic nephropathy. We will provide an update on our plans for XL784 once we complete our analysis of the data."

The complete safety and efficacy data from the phase 2 trial of XL784 in diabetic patients with proteinuria are scheduled for presentation on November 2, 2007, at the American Society of Nephrology (ASN) Renal Week 2007, which is being held in San Francisco from October 31 - November 5, 2007. In addition, following the presentation, Exelixis will hold a briefing for analysts and investors from 12:15 PM - 1:15 PM, Pacific Daylight Time, at the W Hotel in San Francisco, CA on Friday, November 2, 2007. This briefing will be webcast and may be accessed by visiting the Events page under the Investors section of the Exelixis website (http://www.exelixis.com). An audio replay of the webcast will also be available until 8:59 PM PT/11:59 PM ET on December 2, 2007. To access this replay, participants may dial 1-888-286-8010 (domestic) or 1-617-801-6888 (international) and use passcode 98351402.

The results of the XL784 phase 2 trial meet the criteria for submission of the compound to GlaxoSmithKline (GSK) for evaluation under the product development and commercialization agreement between Exelixis and GSK. Pursuant to the agreement, GSK has the option, subject to criteria specified in the agreement, to elect to develop and commercialize up to three compounds in Exelixis' product pipeline from among XL784, XL880, XL184, XL820, XL999, XL844, XL228, XL281 and XL418. Exelixis expects to submit the data package to GSK by the end of October, after which GSK will have 90 days to review the data package and determine if it will select the compound for further clinical development and commercialization.

XL784 is also part of Exelixis' clinical development financing arrangement with Symphony Evolution, Inc. (SEI). In 2005, Exelixis licensed three of its compounds, XL784, XL647 and XL999, to SEI in return for $80 million for the clinical development of these compounds and an exclusive option to reacquire the compounds from SEI's investors at a specified purchase price. Exelixis is primarily responsible for the development of these compounds in accordance with specified development plans and related development budgets.

About the Trial

The multi-site phase 2 trial of XL784 was designed to enroll approximately 130 diabetic patients who have clinically significant proteinuria. Participants were randomly assigned to receive 200mg of XL784 or placebo daily for three months. The primary endpoint of the trial was a significant reduction in proteinuria compared with placebo. Secondary endpoints included changes in renal function and cardiovascular events.

About XL784

XL784 was the first small molecule compound developed by Exelixis, using its proprietary drug discovery engine. The compound is a potent inhibitor of the ADAM-10 and MMP-2 metalloprotease enzymes, targets of significant interest because of their important role in renal fibrosis and impairment. XL784 was specifically optimized to be matrix metalloprotease-1 (MMP-1) sparing, thus potentially significantly enhancing its safety profile and enabling higher dosing compared with other previously studied metalloprotease inhibitors. Results of single and repeat dose phase 1 clinical trials of XL784 administered orally to 70 healthy volunteers demonstrated that XL784 has attractive safety and pharmacokinetic profiles.

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 2 and phase 1 clinical development for cancer and renal disease. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including GSK, Bristol-Myers Squibb, Genentech, Wyeth Pharmaceuticals and Daiichi-Sankyo. For more information, please visit the company's web site at http://www.exelixis.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to the future development and potential efficacy, safety and tolerability of XL784 and the timing of the submission of XL784 data to GSK. Words such as "may," "will," "expects" 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 results of any failure of XL784 to demonstrate safety and efficacy in clinical testing, risks related to Exelixis' arrangement with SEI and Exelixis' dependence on and relationship with GSK. These and other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' Quarterly Report on Form 10-Q for the quarter ended June 30, 2007 and Exelixis' 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 Exelixis' 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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