Phase 2 Trial Results for Exelixis' XL784 Presented at the 2007 American Society of Nephrology Conference

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SAN FRANCISCO, Nov. 2 /PRNewswire-FirstCall/ -- Exelixis, Inc. (Nasdaq: EXEL) today presented data from its phase 2 clinical trial of XL784 in subjects with albuminuria due to diabetic nephropathy. XL784 is a small molecule inhibitor of ADAM-10 and MMP-2, metalloprotease enzymes that may play a role in the pathogenesis of diabetic nephropathy and renal fibrosis. The data were presented during a poster session (Abstract/Poster PO1030) at the American Society of Nephrology Renal Week 2007 meeting in San Francisco. The company previously announced that the clinical trial did not meet its primary endpoint.

125 subjects were enrolled into this randomized, double-blind, placebo-controlled study. XL784 (200mg once daily for 12 weeks) was compared to placebo in subjects with macro-albuminuria who were being treated concurrently with an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB).

The primary endpoint was the reduction from baseline in the urinary albumin to creatinine ratio (ACR) at Week 12. 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.

After 12 weeks of treatment with XL784 the baseline normalized ACR (end of treatment/baseline ACR) in the XL784 group was 9.9% lower than that in the placebo group (not significant). There was a clinically relevant mean ACR reduction from baseline of 23% (p=0.0027) in subjects randomized to XL784. The change in glomerular filtration rate (GFR) at Week 12 was -2.5 ml/min/1.73m2 in the XL784 group and -6.2 ml/min/1.73m2 in the placebo group (p=0.077).

In an exploratory analysis, subjects were stratified according to dose of ACEi and/or ARB received (as a percentage of the maximum FDA recommended dose). The benefit of XL784 compared to placebo increased with increasing dose of ACEi and/or ARB. In the subgroup of subjects treated with maximum recommended doses of ACEi and/or ARB, the difference between XL784 and placebo was 23% (p=0.13) for the primary analysis population.

XL784 was generally well-tolerated, with fewer subjects reporting adverse events in the XL784 group (77%) than in the placebo group (85%). Serious adverse events (SAEs) were reported by 9.5% of subjects in the XL784 group and by 11% of subjects in the placebo group. No SAEs in the XL784 group were considered to be related to study drug.

"We are pleased to report the data from the XL784 trial in patients with diabetic nephropathy," said George A. Scangos, PhD, president and chief executive officer of Exelixis. "While the trial did not meet its primary endpoint, various subgroup analyses suggest that the compound may have the potential to benefit patients with this disease. We submitted the XL784 data package to GSK on October 22, 2007 and expect to communicate future plans for XL784 once GSK has reached a decision on its interest in further developing the compound."

The previously announced briefing to be held today in conjunction with the presentation of the data for XL784 has been cancelled. However, we expect to discuss the data during the live webcast of our third quarter financial results and general business updates to be held on Monday, November 5, 2007 at 2:00 p.m. PST/5:00 p.m. EST. The webcast may be accessed in the Event Calendar page under Investors at http://www.exelixis.com. In addition, we will discuss the data for XL784 at our Third Annual R&D Day on December 5, 2007 to be held in New York.

About XL784

XL784 is 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 safety and efficacy of XL784. Words such as "may," "expect," "suggest," "potentially" 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.

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