Exelixis Reaches Pre-Specified Number of Events for Final Data Analysis in EXAM Trial

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SOUTH SAN FRANCISCO, Calif., Sep 07, 2011 (BUSINESS WIRE) -- Exelixis, Inc. (Nasdaq: EXEL) today announced that the pre-specified number of progression-free survival (PFS) events required for un-blinding of the data for the ongoing phase 3 pivotal trial of cabozantinib in patients with medullary thyroid cancer (MTC), known as the EXAM trial, has been reached. Final data analysis in preparation for un-blinding is underway, and the company expects to report top-line data early in the fourth quarter of 2011.

"We are pleased to have reached this important milestone in the EXAM trial and to now be finalizing our internal work to report top-line results of this important phase 3 trial for Exelixis," said Michael Morrissey, president and chief executive office of Exelixis. "We view MTC as the first building block in the cabozantinib franchise, which we expect to complement with the planned initiation of our pivotal trial in castration-resistant prostate cancer later this year."

EXAM Trial Design

EXAM is an international, randomized, placebo-controlled, double-blinded study of cabozantinib in patients with unresectable, locally advanced, or metastatic MTC. Patients with documented progressive disease were randomized in a 2:1 ratio to receive cabozantinib or placebo administered at a daily dose of 175 mg. The study does not allow for cross-over from the placebo arm to cabozantinib. With an enrollment target of 315 patients and a planned event-driven analysis, the trial provides 90% power to detect a 75% increase in progression-free survival, the primary endpoint of the study. Additionally, the study is designed to assess overall survival at a later time point once those events have been achieved, and is powered to detect a 50% improvement in survival compared with placebo. Exelixis is conducting this trial under a Special Protocol Assessment from the FDA, which allows for full approval on the basis of PFS if the data are supportive. EXAM completed enrollment in the first quarter of 2011.

About Exelixis

Exelixis, Inc. is a biotechnology company committed to developing small molecule therapeutics for the treatment of cancer. Exelixis is focusing its resources and development efforts exclusively on cabozantinib, its most advanced solely-owned product candidate, in order to maximize the therapeutic and commercial potential of this compound. Exelixis believes cabozantinib has the potential to be a high-quality, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. Exelixis has also established a portfolio of other novel compounds that it believes have the potential to address serious unmet medical needs. 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 continued development and clinical, therapeutic and commercial potential of cabozantinib; the expected timing for reporting top-line data in the EXAM trial; the belief that MTC is in the initial building block in the cabozantinib franchise; and the planned initiation of the first pivotal trial of cabozantinib in castration-resistant prostate cancer. Words such as "expects," "view," "planned," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs, and 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, risks related to: the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the availability of data at the referenced times; the sufficiency of Exelixis' capital and other resources; the uncertain timing and level of expenses associated with the development of cabozantinib; the uncertainty of the FDA approval process; market competition; and changes in economic and business conditions. These and other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' quarterly report on Form 10-Q for the quarter ended July 1, 2011, and other filings with the Securities and Exchange Commission. Exelixis expressly disclaims any duty, 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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