Exelixis Provides Update on Cabozantinib Development Activities

July 6, 2011

Timeline for reporting top-line data from EXAM extended by approximately three months
Protocol for XL184-306 pivotal trial in CRPC submitted to FDA for review
Management to hold conference call at 6:00 p.m. EDT/3:00 p.m. PDT today

SOUTH SAN FRANCISCO, Calif., Jul 06, 2011 (BUSINESS WIRE) --

Exelixis, Inc. (NASDAQ:EXEL) today announced an update to the timing for reporting top-line data from the ongoing phase 3 pivotal trial of cabozantinib in patients with medullary thyroid cancer (MTC), known as the EXAM trial. The company has extended the timing to report top-line data from this trial by approximately three months. The timeline is being extended from the middle of this year to provide additional time for the trial to reach the pre-specified number of progression-free survival (PFS) events required for un-blinding of the data.

"We continue to be optimistic about a positive outcome for the EXAM trial. We believe the activity that cabozantinib has demonstrated in MTC as part of the ongoing phase 1 clinical trial of cabozantinib in this indication as well as the selection of MTC patients with rapidly progressing disease increase the possibility of a positive outcome for the EXAM study," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "We also continue to advance the development program in castration-resistant prostate cancer (CRPC). The protocol for the XL184-306 pivotal trial using a combined endpoint of pain reduction and bone scan response was submitted to the U.S. Food and Drug Administration (FDA) in June for consideration of a special protocol assessment (SPA) and our goal is to initiate this trial by the end of 2011. Additionally, we are planning the XL184-307 and XL184-308 pivotal trials in the CRPC for overall survival and bone metastasis-free survival respectively and expect to initiate both of these trials in 2012."

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 are 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 SPA 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.

EXAM Patient Population

To best assess cabozantinib's ability to impact progressive disease, enrollment in the EXAM trial was restricted to patients with rapidly progressing MTC, which was defined as evidence of progressive disease per RECIST comparing the baseline scan with an assessment obtained within the previous 14 months. Medullary thyroid cancer typically follows a slow path of progression, and patients may live for a period of years without their condition worsening. Patients after surgery who have stage I disease have median survival in excess of 10 years. Median survival in patients with stage IV disease (metastatic MTC) is two years. It is expected that median survival in EXAM's patient population would be less than two years given that their disease is unresectable, locally advanced, or metastatic MTC that is actively progressing.

Phase 1 Experience in MTC

Data from the ongoing phase 1 clinical trial have been presented at several oncology and thyroid meetings over the past few years and the phase 1 clinical data was recently published in the *Journal of Clinical Oncology* in late May of this year. Investigators are still following a number of patients who are on continued study treatment.

The phase 1 trial enrolled a total of 37 patients with 35 patients being response evaluable. It showed a 29% rate of confirmed partial responses. These responses were generally durable with a response duration of up to 48+ months per the most recent update. Four patients are in continued response at the current time. Additionally, 15 patients (41%) had stable disease lasting longer than 6 months with some patients continuing on study 3+ years after study initiation. Activity was independent of both RET mutation status and prior treatment with tyrosine kinase inhibitors, including vandetanib.

NDA Filing Plans for MTC

As previously reported, the FDA has granted cabozantinib orphan drug designation and fast track status for MTC, and the latter confers several important benefits, including the potential ability to file a rolling New Drug Application (NDA). Given the extension of the timing for the un-blinding of the EXAM trial, Exelixis now plans to initiate a rolling submission in the fourth quarter 2011 by submitting key parts of the NDA, including the preclinical and chemistry, manufacturing and controls (CMC) information later this year, and expects to complete the file in the first quarter of 2012. Assuming a positive outcome in the EXAM trial, the Company currently anticipates a commercial launch of cabozantinib in MTC in the second half of 2012.

Conference Call and Webcast Information

Exelixis' management will discuss the updated timeline for reporting top-line data from EXAM and provide an update on the comprehensive cabozantinib development program in MTC and CRPC during a conference call beginning at 6:00 p.m. EDT / 3:00 p.m. PDT today, Wednesday, July 6, 2011. To listen to a live webcast of the discussion, visit the Event Calendar page under Investors at www.exelixis.com.

An archived replay of the webcast will be available on the Event Calendar page under Investors at www.exelixis.com and via phone until 11:59 p.m. EDT on August 6, 2011. Access numbers for the phone replay are: 888-286-8010 (domestic) and 617-801-6888 (international); the passcode is 50152278.

About Cabozantinib

Cabozantinib is a potent, dual inhibitor of MET and VEGFR2. Cabozantinib is an investigational agent that provides coordinated inhibition of metastasis and angiogenesis to kill tumor cells while blocking their escape pathways. The therapeutic role of cabozantinib is currently being investigated across several tumor types. MET is upregulated in many tumor types, thus facilitating tumor cell escape by promoting the formation of more aggressive phenotypes, resulting in metastasis. MET-driven metastasis may be further stimulated by hypoxic conditions in the tumor environment, which are often exacerbated by selective VEGF-pathway inhibitors. In preclinical studies, cabozantinib has shown powerful tumoricidal, antimetastatic and antiangiogenic effects, including:

- Extensive apoptosis of malignant cells
- Decreased tumor invasiveness and metastasis
- Decreased tumor and endothelial cell proliferation
- Blockade of metastatic bone lesion progression
- Disruption of tumor vasculature

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 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 timeline for the ongoing phase 3 pivotal trial of cabozantinib in MTC, including the timing for reporting top-line data, the timing for submitting an NDA and the anticipated timing for the commercial launch of cabozantinib in MTC; the possibility of a positive outcome in the phase 3 pivotal trial of cabozantinib in MTC; Exelixis' goal to initiate the first pivotal trial of cabozantinib in CRPC (XL184-306) by the end of 2011; and the planning for two additional pivotal trials in CRPC (XL184-307 and XL184-308) and Exelixis' expectation to initiate these trials in 2012. Words such as "extended," "optimistic," "possibility," "goal," "planning," "plans," "expect," "would," "potential," "anticipates," "believes," 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 April 1, 2011 and Exelixis' 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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