Exelixis Expands the Cabozantinib Development Program Through NCI-CTEP Collaboration

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-- Initial Program of 12 Additional Trials, Including Four Randomized Phase 2 Trials, Approved under NCI-CTEP Collaboration --

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May. 3, 2012-- Exelixis, Inc. (NASDAQ:EXEL) today announced a broad expansion of the cabozantinib development program under a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's Cancer Therapy Evaluation Program (NCI-CTEP), with the approval of the initial program of 12 proposed clinical trials under the agreement. The CRADA provides for funding for as many as 20 active clinical trials each year for a five year period, which Exelixis believes will allow it to broadly expand the cabozantinib development program in a cost-efficient manner. When initiated, these trials will substantially increase the number of indications and disease settings in which cabozantinib is being investigated and aid in prioritizing the next set of pivotal trials.

Cabozantinib is a potent, first-in-class, tyrosine kinase inhibitor that simultaneously targets the MET and VEGF signaling pathways. In clinical studies, cabozantinib has demonstrated a unique spectrum of anti-tumor activity in 12 out of 13 tumor types tested, with regression of metastatic or primary tumor lesions in soft tissue, visceral organs and the brain, resolution of bone lesions on bone scan, and substantial reductions in pain and narcotic use in patients with castration-resistant prostate cancer (CRPC). Exelixis initiated a rolling submission of a new drug application (NDA) for cabozantinib in medullary thyroid cancer in December 2011 based on the positive top-line results in the phase 3 EXAM trial announced in October 2011. The NDA submission is expected to be completed in the first half of this year. Cabozantinib is currently in phase 3 clinical development in CRPC.

Three groups of initial trials have been approved under the CRADA:

Trials to Prioritize Future Development. Four randomized phase 2 trials have the potential to demonstrate cabozantinib's utility in disease settings where there is substantial unmet medical need. Trials are planned to be conducted in first line renal cell carcinoma, second line hepatocellular carcinoma, platinum-resistant or refractory ovarian cancer, and second line non-small cell lung cancer, all of which are settings in which cabozantinib has previously shown clinical activity. Additional non-randomized phase 2 trials in ocular melanoma and non-small cell lung cancer are expected to further expand the data sets from earlier studies which demonstrated the antitumor activity of cabozantinib in these settings. Results from this group of trials could aid in the prioritization of future phase 3 pivotal trials.

Signal Search Trials to Identify Indications for Further Study. Single arm phase 2 trials are planned to explore cabozantinib's potential in additional tumor types, consisting of trials in endometrial cancer, bladder cancer and sarcoma. Positive results in these indications could lead to further study in randomized phase 2 or phase 3 studies.

Additional Trials. Phase 1 combination trials in additional tumor types are planned as well as a trial to evaluate cabozantinib in pediatric malignancies.

"In Exelixis-sponsored trials, cabozantinib has shown signs of tumor shrinkage in 12 of 13 tumor types studied, including medullary thyroid, prostate, breast, ovarian, and non-small cell lung cancer, melanoma, and hepatocellular carcinoma," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "Our CRADA with NCI-CTEP provides important support for evaluating the full potential of cabozantinib in these and other indications as we focus our internal resources on the late-stage development and potential commercialization of cabozantinib in thyroid and prostate cancers. We are grateful for the support of so many investigators in the oncology community and the staff at NCI-CTEP, and look forward to working with them to advance our understanding of the role that cabozantinib may play in improving outcomes for cancer patients."

The proposed trials approved under the CRADA will be conducted under an investigational new drug application (IND) held by NCI-CTEP. Protocol development for each of the trials is expected to commence shortly and the first of these trials is anticipated to begin in approximately late 2012 or early 2013.

About the CRADA

The CRADA between Exelixis and NCI-CTEP was established in November 2011 and covers up to twenty active clinical trials per year. The agreement reflects a major commitment by NCI-CTEP to support the full exploration of cabozantinib's potential in a wide variety of cancers with substantial unmet medical need. The initial request for proposals from NCI investigators generated intense interest from the oncology community: Exelixis and NCI-CTEP personnel jointly reviewed more than 60 submissions to arrive at the final list of trials.

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 therapies for the treatment of cancer. Exelixis is focusing its proprietary resources and development efforts exclusively on cabozantinib (XL184), its most advanced 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, broadly-active, 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, many of which are being advanced by partners as part of collaborations. 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 timing for completion of the NDA submission for cabozantinib in medullary thyroid cancer; the broad expansion of the cabozantinib development program through the CRADA; the plans and conduct of the parties to, and scope, goals and expected benefits of, the CRADA; the design, conduct, goals and other expected benefits arising from the first program of approved trials under the CRADA; and the planned initiation of the first program of approved trials under the CRADA, including the anticipated timing thereof. Words such as “expands,” “proposed,” “provides,” “believes,” “will,” “when,” “expected,” “potential,” “planned,” “could,” “support,” “look forward,” “advance,” “may,” “future,” “anticipated,” 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; timely receipt of potential reimbursements, milestones, royalties and profits under Exelixis’ collaborative agreements; Exelixis’ ability to enter into new collaborations; market competition; and changes in economic and business conditions. These and other risk factors are discussed under “Risk Factors” and elsewhere in Exelixis’ annual report on Form 10-K for the fiscal year ended December 30, 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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