Exelixis Signs CRADA With National Cancer Institute to Expand Development Plan of Cabozantinib

November 28, 2011

NCI to send mass solicitation letter to investigators requesting proposals to evaluate cabozantinib across multiple solid tumor indications in pediatric and adult patients

SOUTH SAN FRANCISCO, Calif., Nov 28, 2011 (BUSINESS WIRE) --

Exelixis, Inc. (Nasdaq: EXEL) today announced that it has entered into a Cooperative Research and Development Agreement (CRADA) with the National Cancer Institute's Cancer Therapy Evaluation Program (CTEP) for further evaluation of cabozantinib, Exelixis' lead compound, in a variety of solid tumors. Cabozantinib is a potent, dual inhibitor of MET and VEGFR2. Exelixis recently announced positive phase 3 data in the EXAM trial in medullary thyroid cancer and that the company is initiating pivotal phase 3 trials in castration-resistant prostate cancer.

The agreement covers up to twenty active clinical trials per year over the lifetime of the CRADA. Under the terms of the CRADA, Exelixis and the National Cancer Institute (NCI) will undertake a series of clinical trials to evaluate the safety and efficacy of cabozantinib in several cancers based upon encouraging anti-tumor activity observed in earlier studies. The trials will be designed to address a number of scientific questions such as how the efficacy of cabozantinib compares with other VEGFR2 inhibitors, the ability of cabozantinib to overcome resistance of tumors to VEGFR2 or EGFR inhibition, and the mechanism of activity of cabozantinib in tumors metastatic to bone.

As data from the CTEP-sponsored studies and other Exelixis-sponsored trials emerge, the NCI and Exelixis will discuss additional trials to complement and support the development of cabozantinib. The NCI may also support non-clinical studies that focus on identifying assays for monitoring the biologic activity of cabozantinib, as well as combination studies of the compound with other targeted agents. Any additional studies will be with mutual agreement and approval of both parties.

"Our CRADA with the NCI's Division of Cancer Treatment and Diagnosis reinforces our commitment to maximize the broad clinical potential of cabozantinib in a wide variety of tumor indications while focusing our own internal efforts on prostate and thyroid cancer," said Michael M. Morrissey, PhD, Exelixis' president and chief executive officer. "As we prepare to file our new drug application with the FDA for the medullary thyroid cancer indication, and continue to advance our pivotal trial plans in prostate cancer, we have found an exemplary partner in the NCI to drive clinical research in other key areas. We hope the CTEP collaboration will provide additional clinical data that will highlight cabozantinib's differentiated clinical profile in multiple different cancer indications."

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 proprietary 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, and opportunities for, cabozantinib; the further evaluation of cabozantinib in a variety of solid tumors; the plans and conduct of the parties to, and goals and expected benefits of, the CRADA; the plan to undertake a series of clinical trials to evaluate the safety and efficacy of cabozantinib in several cancers based upon encouraging anti-tumor activity observed in earlier studies; potential additional trials to complement and support the development of cabozantinib; potential non-clinical studies and combination studies; design and goals of future trials conducted under the CRADA; Exelixis' commitment to maximize the broad clinical potential of cabozantinib; plans to focus Exelixis' internal resources

on prostate and thyroid cancer; plans to initiate pivotal trials of cabozantinib in prostate cancer; plans to file a new drug application for cabozantinib in medullary thyroid cancer; and cabozantinib's differentiated clinical profile in multiple different cancer indications. Words such as "further," "will," "encouraging," "may," "commitment," "prepare," "continue," "advance," "potential," "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 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 September 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.

Exelixis, Inc.
Charles Butler, 650-837-7277
Vice President
Corporate Communications & Investor Relations
cbutler@exelixis.com