Exelixis Regains Full Rights to Develop and Commercialize XL184

June 21, 2010

-Broad Development Plan Expected to Continue-

SOUTH SAN FRANCISCO, Calif., Jun 21, 2010 (BUSINESS WIRE) --Exelixis, Inc. (Nasdaq:EXEL) today announced that it has regained full rights to develop and commercialize XL184. Exelixis and Bristol-Myers Squibb Company (BMS) entered into a global development collaboration for XL184, the clinically most advanced MET inhibitor, in December 2008. Under the agreement, BMS and Exelixis had originally agreed to certain clinical development plans, and Exelixis maintained key rights regarding timing and funding of current and future clinical trials. Given the recent progress of BMS' wholly-owned oncology pipeline and positive data generated by XL184, Exelixis and BMS were not able to align on the scope, breadth and pace of the ongoing clinical development of XL184. As a result, BMS returned XL184 to Exelixis, thereby giving Exelixis the opportunity to advance the program as originally envisioned. BMS will make a payment to Exelixis of $17 million in connection with the return of XL184.

"We believe in the clinical and commercial potential of XL184 in a broad array of cancer indications. The data that we recently presented at ASCO were encouraging," said George A. Scangos, Ph.D., president and chief executive officer of Exelixis. "We certainly understand BMS' need to make pipeline and prioritization decisions, but from Exelixis' perspective, XL184 is our most advanced compound, the data are encouraging, and we need to rapidly develop the compound in indications justified by the data, including medullary thyroid cancer, glioblastoma, and potentially some of the major tumor types being evaluated in the randomized discontinuation trial. We regret BMS' decision, but we are pleased to now have the opportunity to develop XL184 independent of divergent pipeline and portfolio considerations. It is a sign of the strength of our relationship that we could achieve this outcome for XL184 at the same time that we continue our positive collaborations around a number of other compounds. We have the resources to take XL184 forward on our own for some time and we see several attractive longer term options, which we are currently evaluating."

XL184 Clinical Development Program

XL184 is currently being evaluated in 13 tumor types across multiple clinical trials. As recently reported at the 2010 Annual Meeting of the American Society of Clinical Oncology (ASCO) in early June, in an expanded cohort in phase 1 of patients with medullary thyroid cancer, XL184 demonstrated a 29% response rate, with a median duration of response that had not yet been reached, with a range of 4 to 35+ months. XL184 is currently being evaluated in a pivotal phase 3 clinical trial in patients with medullary thyroid cancer. Assuming positive results from the pivotal trial, Exelixis anticipates submitting a new drug application (NDA) with the Food and Drug Administration for XL184 in this indication in 2011. Also as reported at the 2010 ASCO Annual Meeting, in a phase 2 clinical trial in patients with recurrent glioblastoma, XL184 demonstrated a 30% response rate when dosed at 125 mg daily, with a median duration of response of 5.1 months. Exelixis expects to initiate a phase 3 pivotal trial in recurrent glioblastoma in the year-end 2010 time frame. In addition, as reported at the 2010 ASCO Annual Meeting, objective responses with XL184 have been observed in patients with refractory melanoma, non-small cell lung cancer (NSCLC) (both as a single agent and in combination with erlotinib), hepatocellular carcinoma, prostate and ovarian cancers in an ongoing adaptive randomized discontinuation trial (RDT). Exelixis expects to prioritize tumor types from the RDT for further development early in 2011.

The detailed safety and efficacy data regarding XL184 reported at the 2010 ASCO Annual Meeting are available in the four XL184 press releases issued by Exelixis on May 20, 2010, which are available under "Investors" on Exelixis' website, www.exelixis.com.

About XL184

XL184 is an investigational oral inhibitor of MET, VEGFR2, and RET that produces antiangiogenic, antiproliferative, and antiinvasive effects in preclinical tumor models. MET is mutationally activated in some tumor types, such as hereditary and sporadic papillary renal cell carcinoma and some head and neck cancers. More frequently, MET is either over-expressed or activated in the absence of mutation in glioblastomas, breast carcinomas, some gastric cancers, and other solid tumors. MET amplification has been demonstrated in some NSCLCs. Expression of VEGF has been observed in a variety of cancers and has been associated with prognostic significance. Targeting the VEGF receptor has been recognized as a potential anti-cancer strategy in multiple tumors. Dual targeting of MET and VEGFR2 blocks two of the major mechanisms tumors use to overcome hypoxia. Activated RET is involved in cell signaling cascades that regulate cell proliferation, migration, differentiation, and survival. RET is mutationally activated in papillary thyroid cancer (PTC) and in both familial and sporadic forms of medullary thyroid cancer (MTC).

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 biological expertise and integrated research and development capabilities to generate a pipeline of development compounds with significant therapeutic and commercial potential for the treatment of cancer and potentially other serious diseases. Currently, Exelixis' broad product pipeline includes investigational compounds in phase 3, phase 2, and phase 1 clinical development. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including Bristol-Myers Squibb Company, sanofi-aventis, GlaxoSmithKline, Genentech (a wholly owned member of the Roche Group), Boehringer Ingelheim, 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, all statements related to the future clinical development of and regulatory submissions with respect to XL184 and other Exelixis compounds (including the timing thereof), the clinical, therapeutic and commercial potential of XL184, the receipt of $17 million from BMS, the sufficiency of Exelixis' financial and other resources to take XL184 forward on its own for some time and Exelixis' ability to execute longer term options for financing the XL184 development program. Words such as "expects," "will," "potential," "opportunity," "anticipates" 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 sufficiency of Exelixis' capital, including risks related to satisfaction by Exelixis of its obligations under its loan from GlaxoSmithKline, the risk that the closing of the previously announced transaction with Deerfield will not occur on the anticipated timing, or at all, due to potential failure to satisfy the conditions to closing, and the risk that if additional capital is not available to Exelixis, it would be forced to delay, reduce or eliminate its product development programs efforts and may breach its financial covenants; the potential failure of XL184 and other Exelixis compounds to demonstrate safety and efficacy in future clinical testing; Exelixis' dependence on current and anticipated future collaborations; Exelixis' ability to conduct clinical trials for its compounds sufficient to achieve a positive completion; regulatory approval of and competition related to Exelixis' compounds and the uncertain timing and level of expenses associated with the development of Exelixis' programs. 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 2, 2010 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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