Exelixis and Bristol-Myers Squibb Report New Phase 2 Data for XL184 in Patients With the Most Common and Aggressive Form of Brain Cancer

October 23, 2009

Data Presented at the 2009 Joint Meeting of the Society for Neuro-Oncology and the AANS/CNS Section on Tumors

SOUTH SAN FRANCISCO, Calif. & NEW YORK--(BUSINESS WIRE)--Oct. 23, 2009-- Exelixis, Inc. (Nasdaq:EXEL) and Bristol-Myers Squibb Company (NYSE:BMY) today reported updated phase 2 clinical data which show that XL184 demonstrated activity in patients with glioblastoma multiforme (GBM), the most common and aggressive form of brain cancer.

The data from study XL184-201 were presented today during a poster session at the 2009 Joint Meeting of the Society for Neuro-Oncology and the AANS/CNS Section on Tumors.

The study evaluates the safety, tolerability, and clinical activity of XL184 at continuous daily doses of 175 mg or 125 mg in patients with previously treated GBM, including some patients who had received prior antiangiogenic therapy. A total of 46 patients in first or second relapse were enrolled and dosed with 175 mg of XL184 administered daily, and enrollment at this dose level is complete. Due to frequent dose interruptions and reductions, the study was amended earlier this year to initiate a new cohort of patients receiving 125mg. As of October 12, 2009, 38 patients have been enrolled at the 125 mg dose level with 18 patients with at least one IRF read post baseline scan.

Tumor response was determined by an independent and blinded radiology facility (IRF) per modified MacDonald criteria. As of September 25, 2009, the overall rate of confirmed partial response in the intent-to-treat population of all patients treated at 175 mg was 8/46 (17%). Among patients without prior antiangiogenic therapy, 7 of 34 (21%) achieved confirmed responses. In patients who had received prior antiangiogenic therapy, 1 of 12 (8%), a patient who had progressed on vandetinib, achieved a confirmed partial response. Of the 46 patients treated at the 175 mg dose level, 21% attained 6-month progression-free survival (PFS) rate with 16/46 (35%) patients censored for PFS at the time of analysis. The median duration of response was 5.9 months. The median PFS interval was 3.7 months.

Follow up for the patients receiving 125 mg is relatively short, with the first patient enrolled in late June 2009. Of the 38 patients enrolled at the 125 mg dose level as of October 12, 2009, 18 patients had at least one post-baseline scan available that had undergone IRF evaluation. Of these 18 patients, 7 have discontinued treatment -- 4 due to progressive disease/clinical deterioration per investigator and 3 due to adverse events. Of 14 antiangiogenic naïve patients enrolled at this dose level, eight have had tumor shrinkage of more than 50% as determined by IRF, including two confirmed partial responses by IRF.

The safety experience, to date, is primarily derived from the 175 mg dose level. The most frequently occurring Grade 3 and Grade 4 adverse events (>5%) regardless of relationship to drug were: fatigue, headache, palmar-plantar erythrodysesthesia, confusional state, alanine aminotransferase increase, convulsion, lymphopenia, hypophosphatemia, lipase increase, diarrhea, aspartate aminotransferase increase, and gait disturbance. Incidence of Grade 3 or 4 adverse events often associated with antiangiogenic therapy were: hypertension (2%), bleeding events (9%), thromboembolic event (4%), pulmonary embolism (7%), craniotomy wound dehiscence (4%), and perirectal abscess (2%). Of the 46 patients treated at the 175 mg dose level, 13 have had at least one serious adverse event (SAE) related to XL184. In addition, 89% of patients at this dose level had a dose interruption of XL184. Dose interruptions (14/18) and reductions (6/18) were observed in patients at the 125 mg dose level. The most frequent investigator reported non-serious adverse events resulting in dose reduction or interruption included: fatigue, palmar-plantar erythrodysesthesia, transaminase elevation, lipase and amylase elevation, and mucositis.

“The updated data from patients treated with the 175 mg dose of XL184 is consistent with what we have reported previously and continue to demonstrate that the compound is clinically active,” said Michael M. Morrissey, Ph.D. president of research and development at Exelixis. “While the data from the 125 mg dose cohort are still early, they are encouraging and we will continue to evaluate the suitability of this dose and potentially others for future clinical studies. We recently amended the protocol for this trial to allow physicians to intervene earlier in the adverse event process. We believe that more proactive management of adverse events may allow patients to reduce rather than interrupt their XL184 dosing. This trial in its totality is providing important information that will enable future decision making with respect to designing and implementing trials of XL184 in this patient population.”

About XL184

XL184 (BMS-907351) 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). Exelixis is co-developing XL184 with Bristol-Myers Squibb Company, and is currently conducting multiple clinical studies with XL184.

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 fully integrated drug discovery platform to fuel the growth of its development pipeline, which is primarily focused on cancer. 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, sanofi-aventis, GlaxoSmithKline, Genentech, Boehringer Ingelheim, Wyeth Pharmaceuticals, and Daiichi-Sankyo. For more information, please visit the company's web site at www.exelixis.com.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company that discovers, develops and delivers medicines that help people prevail over serious diseases. For more information, visit www.bms.com.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements by Exelixis, including, without limitation, statements related to the continued demonstration of clinical activity of XL184 from patients treated with the 175mg dose; Exelixis' plan to continue to evaluate the suitability of the 125mg dose and potentially others for future clinical studies; Exelixis' belief that more proactive management of adverse advents may allow patients to reduce rather than interrupt their XL184 dosing; and future decision making with respect to designing and implementing trials of XL184. Words such as "will," "continue," "believe," "future," "may," "potential," 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 XL184 to demonstrate safety and efficacy in clinical testing and Exelixis' ability to conduct clinical trials of XL184 in patients with GBM sufficient to achieve a positive completion. 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 3, 2009 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.

Bristol-Myers Squibb Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 relating to the development and commercialization of certain compounds. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that the clinical trial mentioned in this release will support a regulatory filing or that the compound will receive regulatory approval or become a commercially successful product. Forward-looking statements in the press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb's business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb's Annual Report on Form 10-K for the year ended December 31, 2008, its Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

Source: Exelixis, Inc.

Bristol-Myers Squibb Company
Brian Henry, 609-252-3337
Director, Business Communications
brian.henry@bms.com
or
Exelixis, Inc.
Charles Butler, 650-837-7277
Vice President, Corporate Communications & Investor Relations
cbutler@exelixis.com