Exelixis Announces Positive Overall Survival Results from Phase 3 Pivotal Trial of Cobimetinib in Combination with Vemurafenib in Patients with BRAF V600 Mutation-Positive Advanced Melanoma

October 6, 2015

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 6, 2015-- Exelixis, Inc. (NASDAQ:EXEL) today announced positive overall survival (OS) results from coBRIM, the phase 3 pivotal trial evaluating cobimetinib, a specific MEK inhibitor discovered by Exelixis, in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma carrying a BRAF V600 mutation. Exelixis' collaborator Genentech, a member of the Roche Group, informed the company that coBRIM met its secondary endpoint of demonstrating a statistically significant and clinically meaningful increase in overall survival for patients receiving the combination of cobimetinib and vemurafenib, as compared to vemurafenib monotherapy. Ongoing study monitoring did not identify any new safety signals. Long-term safety data are expected later this year. These data will be the subject of a presentation at an upcoming medical meeting.

"The positive effect of the combination of cobimetinib and vemurafenib on overall survival is a major step forward for patients with advanced BRAF V600 mutation-positive melanoma in search of new treatment options," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "We continue to work with our partners at Genentech in preparation for the potential U.S. approval and launch of cobimetinib to deliver this important potential treatment option to patients, physicians and caregivers in the United States as quickly as possible."

Exelixis announced the first regulatory approval of cobimetinib in Switzerland in August 2015. U.S. and EU regulatory applications sponsored by Genentech and Roche, respectively, are currently under review. In the United States, the Prescription Drug User Fee Act action date is November 11, 2015. In the EU, Roche anticipates a regulatory decision by the end of this year following a positive opinion from the European Committee for Medicinal Products for Human Use announced in late September.

About the coBRIM Study

The coBRIM trial is an international, randomized, double-blind, placebo-controlled Phase III study evaluating the safety and efficacy of 60 mg once daily of cobimetinib in combination with 960 mg twice daily of vemurafenib, compared to 960 mg twice daily of vemurafenib alone. In the study, 495 patients with BRAF V600 mutation-positive unresectable locally advanced or metastatic melanoma (detected by the cobas® 4800 BRAF Mutation Test) and previously untreated for advanced disease, were randomized to receive vemurafenib every day on a 28-day cycle plus either cobimetinib or placebo for days 1-21. Treatment was continued until disease progression, unacceptable toxicity or withdrawal of consent. Investigator-assessed PFS is the primary endpoint. Secondary endpoints include PFS by independent review committee, overall response rate, overall survival, duration of response and other safety, pharmacokinetic and quality of life measures.

About the Cobimetinib Development Collaboration

Exelixis discovered cobimetinib internally and advanced the compound to investigational new drug (IND) status. In late 2006, Exelixis entered into a worldwide co-development agreement with Genentech, under which Exelixis received initial upfront and milestone payments for signing the agreement and submitting the IND. Exelixis was responsible for development of cobimetinib through the end of phase 1, at which point Genentech exercised its option to further develop the compound.

If cobimetinib is approved in the United States, Exelixis is entitled to an initial equal share of U.S. profits and losses, which will decrease as sales increase, and will share in U.S. marketing and commercialization costs. In November 2013, Exelixis exercised its option to co-promote cobimetinib in the United States and, under the terms of the agreement, the company is prepared to field up to 25 percent of the U.S. sales force.

About the Combination of Cobimetinib and Vemurafenib

Cobimetinib is a selective inhibitor that blocks the activity of MEK, a protein kinase that is part of a key pathway (the RAS-RAF-MEK-ERK pathway) that promotes cell division and survival. This pathway is frequently activated in human cancers including melanoma, where mutation of one of its components (BRAF) causes abnormal activation in about 50 percent of tumors. About 50 percent of patients with BRAF mutation positive melanoma experience a tumor response when treated with a BRAF inhibitor, however development of resistance and subsequent tumor progression limits treatment benefit. Clinical and preclinical analyses indicated that reactivation of the MEK-ERK pathway may underlie development of resistance to BRAF inhibitors in many progressing tumors, and that co-treatment with a BRAF and MEK inhibitor delays the emergence of resistance in the preclinical setting, providing the rationale for testing the combination of vemurafenib and cobimetinib in clinical trials. In addition to the combination with vemurafenib in melanoma, cobimetinib is also being investigated in combination with several investigational medicines, including an immunotherapy, in several tumor types, including non-small cell lung cancer, colorectal cancer, triple-negative breast cancer and melanoma.

About Melanoma and its BRAF V600 Mutation-Positive Form

Melanoma is the less common, but more serious category of skin cancer that starts in the skin's pigment producing cells known as melanocytes. According to the American Cancer Society, approximately five percent of skin cancer diagnoses are melanoma, but melanoma accounts for a large majority of skin cancer deaths. In recent years, there have been significant advances in treatment for metastatic melanoma and people with the disease have more options. However, it continues to be a serious health issue with a high unmet need and a steadily increasing incidence over the past 30 years. It is projected that approximately half of all melanomas, and eight percent of solid tumors, contain a mutation of the BRAF protein. BRAF is a key component of the RAS-RAF-MEK-ERK pathway involved in normal cell growth and survival. However, mutations that keep the BRAF protein in an active state may cause excessive signaling in the pathway, leading to uncontrolled cell growth and survival. The BRAF V600 mutation-positive form of melanoma is associated with high-risk characteristics of the disease, including early onset, the absence of chronic skin damage, and decreased survival.

About Exelixis

Exelixis, Inc. is a biopharmaceutical company committed to developing small molecule therapies for the treatment of cancer. Exelixis is focusing its development and commercialization efforts primarily on cabozantinib, its wholly-owned inhibitor of multiple receptor tyrosine kinases. Another Exelixis-discovered compound, cobimetinib, a selective inhibitor of MEK, received its first regulatory approval in Switzerland and is being evaluated by Roche and Genentech (a member of the Roche Group) in a broad development program under a collaboration with Exelixis. For more information, please visit the company's web site at www.exelixis.com.

Forward-Looking Statement Disclaimer

This press release contains forward-looking statements, including, without limitation, statements related to: the availability of additional data from the coBRIM trial at stated times; the potential for regulatory approvals for cobimetinib by the European Commission in the EU and the FDA in the U.S. by the end of 2015; the potential for cobimetinib to advance melanoma treatment; Exelixis' preparedness to support U.S. co-promotion efforts for cobimetinib in the U.S.; the plan of Genentech and Exelixis to share U.S. profits and losses and U.S. marketing and commercialization costs for cobimetinib; and, Exelixis' potential receipt of royalties on sales of cobimetinib products outside the U.S. Words such as "expect," "will," "continue to," "prepare," "potential," "as quickly as possible," "anticipate," "if," or other similar expressions, identify forward-looking statements, but the absence of these words does not necessarily mean that a statement is not forward-looking. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs, expectations, and projections. Exelixis' actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of risks and uncertainties, which include, without limitation: risks related to: the clinical, therapeutic and commercial value of cobimetinib; Exelixis' dependence on its relationship with Genentech/ Roche with respect to cobimetinib and Exelixis' ability to maintain its rights under the collaboration; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; market competition; changes in economic and business conditions; and other factors discussed under the caption "Risk Factors" in Exelixis' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 11, 2015 and in Exelixis' other filings with the SEC. The forward-looking statements made in this press release speak only as of the date of this press release. 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.

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