Exelixis' Collaborator Genentech Files New Drug Application for the Combination of Cobimetinib and Vemurafenib for the Treatment of Patients With BRAF V600 Mutation-Positive Advanced Melanoma

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Dec. 15, 2014-- Exelixis, Inc. (NASDAQ:EXEL) today announced its collaborator Genentech, a member of the Roche Group, has completed the filing of its New Drug Application (NDA) with the U.S. Food and Drug Administration (FDA) for cobimetinib, a specific MEK inhibitor discovered by Exelixis, in combination with vemurafenib for previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600 mutation. Cobimetinib has received Fast Track designation by the FDA. Roche submitted a Marketing Authorization Application for the combination to the European Medicines Agency in September of this year.

The NDA is based on data from the coBRIM trial, a phase 3 pivotal trial conducted by Genentech in 495 patients with BRAF V600 mutation-positive unresectable locally advanced or metastatic melanoma. As presented during the Presidential Symposium at the European Society for Medical Oncology 2014 Congress, coBRIM met its primary endpoint, demonstrating a statistically significant increase in investigator-determined progression-free survival (PFS). The median PFS was 9.9 months for the combination of cobimetinib and vemurafenib versus 6.2 months for vemurafenib alone (hazard ratio [HR] = 0.51, 95 percent CI 0.39-0.68; $p < 0.0001$). The safety profile of the combination was consistent with that observed in a previous study of the combination. The most common Grade 3 or higher adverse events in the combination arm included liver lab abnormalities, elevated creatine phosphokinase and diarrhea. The most common adverse events seen in the combination arm included diarrhea, nausea, rash, photosensitivity and lab abnormalities.

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 in connection with signing the agreement and submitting the IND. Exelixis was responsible for development of cobimetinib through the determination of the maximum tolerated dose in phase 1, at which point Genentech exercised its option to further develop the compound.

In November 2013, Exelixis exercised its option to co-promote cobimetinib, if 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 equally in the U.S. marketing and commercialization costs. Exelixis is eligible to receive royalties on any sales of the product outside the United States.

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 COMETRIQ® (cabozantinib), its wholly-owned inhibitor of multiple receptor tyrosine kinases. Another Exelixis-discovered compound, cobimetinib, a highly selective inhibitor of MEK, 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 Statements

This press release contains forward-looking statements, including, without limitation, statements related to: potential regulatory approval for cobimetinib; Exelixis' future U.S. co-promotion efforts for cobimetinib in the United States; the plan of Genentech and Exelixis to share U.S. profits and losses for cobimetinib and U.S. marketing and commercialization costs for cobimetinib; and Exelixis' potential receipt of royalties on sales of cobimetinib products outside the United States. Words such as "if," "entitled," "will," "eligible," 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, estimates and projections. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in the forward-looking statements as a result of these 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 November 4, 2014 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.

Source: Exelixis Inc.

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