



Exelixis Provides Update on Genentech's Pending New Drug Application for Cobimetinib, an Exelixis-Discovered Compound

July 1, 2015

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 1, 2015-- Yesterday, Exelixis' (NASDAQ:EXEL) partner Genentech, a member of the Roche Group, informed Exelixis that, in order to accommodate its review of a supplemental data submission, the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) action date for its review of Genentech's New Drug Application (NDA) for cobimetinib by the standard extension period of three months, from August 11, 2015 to November 11, 2015.

FDA extended its review after Genentech submitted, at FDA request, additional data from coBRIM, the phase 3 registrational trial of cobimetinib and vemurafenib in patients with BRAF V600 mutation-positive advanced melanoma.

Exelixis discovered cobimetinib, a selective inhibitor of MEK, internally and advanced the compound to investigational new drug (IND) status. In late 2006, Exelixis entered into a collaboration 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 the Cobimetinib and Vemurafenib Combination

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% of tumors. Tumors with BRAF mutations may develop resistance and subsequently progress after treatment with a BRAF inhibitor. In preclinical melanoma models, co-treatment with a BRAF inhibitor and a MEK inhibitor may delay the emergence of resistant tumors. 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 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 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 April 30, 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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