European CHMP Adopts Positive Opinion for Cobimetinib in Combination with Vemurafenib for the Treatment of Advanced Melanoma

September 25, 2015

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 25, 2015-- Exelixis, Inc. (NASDAQ:EXEL) today announced that the European Medicines Agency's Committee for Medical Products for Human Use (CHMP) has adopted a positive opinion of the Marketing Authorization Application for cobimetinib, a selective MEK inhibitor discovered by Exelixis, in combination with vemurafenib for the treatment of BRAF V600 mutation-positive unresectable or metastatic melanoma. The CHMP's positive opinion will now be reviewed by the European Commission, which has the authority to approve medicines for the European Union. The European Commission is expected to release its final decision regarding the approval of the combination of cobimetinib and vemurafenib by the end of 2015.

"The CHMP's positive opinion on cobimetinib for use in combination with vemurafenib is an important milestone in bringing this new therapeutic option to patients in Europe," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "We congratulate Genentech and Roche on this latest milestone in the European regulatory process. We also look forward to the regulatory decision anticipated this year in the United States, where we are fully prepared to co-promote cobimetinib with our partners."

The CHMP's recommendation is based on data from coBRIM, the international, randomized double-blind controlled phase 3 pivotal trial evaluating cobimetinib in combination with vemurafenib in previously untreated patients with unresectable locally advanced or metastatic melanoma harboring a BRAF V600 mutation.

The combination of cobimetinib and vemurafenib recently received its first approval in Switzerland, where cobimetinib is marketed as Cotellic™.

The coBRIM trial was conducted by Roche and Genentech, a member of the Roche Group. Genentech filed a New Drug Application (NDA) for cobimetinib in the United States, for which the Prescription Drug User Fee Act action date is November 11, 2015.

About the Cobimetinib Development Collaboration

After discovering cobimetinib internally, Exelixis advanced the product to investigational new drug (IND) status. In late 2006, the company entered into its worldwide collaboration with Genentech, under which Exelixis received initial upfront and milestone payments for signing the agreement and submitting the IND. Following the determination of the maximum tolerated dose in phase 1 by Exelixis, Genentech exercised its option to further develop cobimetinib. Under the terms of the collaboration, Exelixis is eligible to receive royalties on sales of cobimetinib outside the United States.

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 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 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 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 Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the potential for regulatory approvals for cobimetinib in EU and U.S. by the end of 2015, including by the FDA in the U.S. and European Commission in the EU; 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," "look forward," "anticipated," "entitled," "eligible," "will," "prepared," 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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