Exelixis Announces Cobimetinib Phase 3 coBRIM Results to Be Presented at ESMO 2014 Congress

September 17, 2014

- Data Accepted for Inclusion in the Presidential Symposium 2 on Monday, September 29, 2014 -

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Sep. 17, 2014-- Exelixis, Inc. (NASDAQ:EXEL) today announced that cobimetinib, an Exelixis-discovered compound, will be the subject of a clinical data presentation at the European Society for Medical Oncology (ESMO) 2014 Congress. During the meeting, which will be held from September 26-30, 2014, in Madrid, Spain, investigators will present initial data from coBRIM, the ongoing phase 3 pivotal trial of cobimetinib in combination with vemurafenib in patients with previously untreated BRAF V600 mutation-positive advanced melanoma.

On July 13, 2014, Exelixis announced positive top-line results from coBRIM after being informed by Genentech, a member of the Roche Group and Exelixis' collaborator, that coBRIM met its primary endpoint, delivering a statistically significant increase in progression-free survival (PFS) for the combination of cobimetinib plus vemurafenib as compared to vemurafenib alone. Roche has indicated that it will initiate regulatory filings for the combination of cobimetinib and vemurafenib before the end of the year.

The ESMO presentation details are as follows:

Abstract Number:	LBA5_PR
Abstract Title:	Phase 3, Double-Blind, Placebo-Controlled Study of Vemurafenib Versus Vemurafenib + Cobimetinib in Previously Untreated BRAFV600 Mutation–Positive Patients With Unresectable Locally Advanced or Metastatic Melanoma (NCT01689519)
Presenter:	Professor Grant McArthur, Peter MacCallum Cancer Centre, Victoria, Australia
Session:	Presidential Symposium 2
Date:	Monday, September 29, 2014
Time:	4:00 – 5:20 p.m. local Madrid time (CEST)

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% 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 vemurafenib and the MEK inhibitor cobimetinib can 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 and colorectal cancer.

About the Collaboration for Cobimetinib

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 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: the continued development and clinical, therapeutic and commercial potential of cobimetinib in combination with vemurafenib and other investigational medicines; future coBRIM data presentations; future regulatory filings and potential approvals; Exelixis' future U.S. co-promotion efforts with Genentech; 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 net sales of cobimetinib products outside the United States. Words such as “will,” “initiate,” “can,” “entitled,” “share,” “estimated,” “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 potential failure of cobimetinib or cabozantinib to demonstrate safety and efficacy in clinical testing; the availability of data at the expected times; the clinical, therapeutic and commercial value of cobimetinib and cabozantinib; 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; the general sufficiency of Exelixis’ capital and other resources and the specific risk of unforeseen expenses that could diminish Exelixis’ financial ability to support its operations through the release of top-line results from METEOR, Exelixis’ phase 3 pivotal trial of cabozantinib in metastatic renal cell cancer; the uncertain timing and level of expenses associated with the development of cabozantinib; risks related to Exelixis’ ability to implement its previously announced workforce reduction according to plan and its impact on Exelixis’ business; charges, expenses and cash expenditures resulting from the referenced workforce reduction; 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 July 31, 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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