Exelixis Announces Genentech Presentation of Preliminary Phase 1b Results for the Combination of Cobimetinib, Vemurafenib and Atezolizumab at ESMO 2016 Congress

October 7, 2016

– Results are the subject of a poster discussion presentation at ESMO 2016 Congress on Monday, October 10 –

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 7, 2016-- Exelixis, Inc. (NASDAQ:EXEL) today announced that its collaborator Genentech, a member of the Roche Group, will present preliminary results from a phase 1b clinical trial evaluating the safety and clinical activity of the triple combination of cobimetinib, vemurafenib, and atezolizumab in patients with previously untreated BRAF V600 mutation-positive advanced melanoma. The results will be the subject of a poster discussion presentation (Abstract #1109PD) at the European Society of Medical Oncology (ESMO) 2016 Congress, which is being held October 7-11 in Copenhagen, Denmark. Patrick Hwu, M.D., chair of the Department of Melanoma Medical Oncology at the University of Texas M.D. Anderson Cancer Center, Houston, Texas, will present the results during a session on Monday, October 10, 2016, beginning at 11:00 a.m. CEST.

"Cobimetinib and vemurafenib is FDA-approved to treat specific forms of BRAF V600 mutation-positive unresectable or metastatic melanoma and has been associated with significant improvements in progression-free survival, overall survival and objective response rate as compared to vemurafenib alone," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "The preliminary results to be presented at the ESMO Congress suggest that adding atezolizumab to the combination regimen is associated both with a manageable safety profile and promising antitumor activity."

The primary objective of the phase 1b trial is the evaluation of the safety and tolerability of the triple combination. Secondary endpoints include progression-free survival (PFS), overall survival (OS), objective response rate (ORR), best overall response, and duration of response, as well as additional exploratory objectives. Patients in the trial receive the triple combination of cobimetinib, vemurafenib, and atezolizumab after a 28-day run-in cycle of combination cobimetinib and vemurafenib. Atezolizumab is administered intravenously at 800 mg every two weeks.

As of the June 15, 2016 data cut-off, 30 patients with previously untreated BRAF V600 mutation-positive unresectable or advanced melanoma who had received at least one dose of atezolizumab were evaluable for safety. The median follow-up for safety was 3.9 months, with a range of 0.7 to 16.8 months. All-grade AEs occurring in greater than 20 percent of patients and reported as related to cobimetinib and/or vemurafenib and/or atezolizumab included elevated liver enzymes, fatigue, arthralgia, diarrhea, flu-like symptoms, photosensitivity, increased blood alkaline phosphatase, fever and pyrexia. Twelve patients had cobimetinib- and/or vemurafenib and/or atezolizumab-related grade 3/4 AEs during the triple combination period; all resolved after appropriate intervention.

Twenty-nine patients had received at least one dose of atezolizumab and undergone at least one on-treatment, post baseline tumor assessment. The ORR, a secondary endpoint, was 83 percent with 24 patients achieving a response (fifteen of which were confirmed as of the data cutoff). Three patients (10 percent) achieved complete responses and 21 patients had partial responses (72 percent). All but one subject in the trial had a reduction of tumor burden. Median duration of response and PFS were not evaluable as a result of limited follow-up time.

Immune biomarkers potentially predictive of clinical responses were evaluated in this phase 1b trial. Increases in CD8+ T cells in the tumor were observed following cobimetinib and vemurafenib treatment during the run-in period.

A pivotal placebo-controlled phase 3 trial evaluating the combination of cobimetinib, vemurafenib and atezolizumab compared to cobimetinib, vemurafenib and placebo was recently posted on ClinicalTrials.gov. Sponsored by Roche, the full title of study NCT02908672 is "A Study of Atezolizumab Plus Cobimetinib and Vemurafenib Versus Placebo Plus Cobimetinib and Vemurafenib in Previously Untreated BRAFv600 Mutation-Positive Participants With Metastatic or Unresectable Locally Advanced Melanoma." Exelixis expects to share additional details of this trial as they become available from its collaborator Roche.

Cobimetinib is a selective inhibitor of MEK that was discovered by Exelixis and is the subject of a worldwide collaboration agreement between Exelixis and Genentech. Cobimetinib is approved in multiple countries to treat specific forms of BRAF V600 mutation-positive unresectable or metastatic melanoma, in combination with vemurafenib. Atezolizumab is an anti-PD-L1 antibody developed by Genentech that received FDA approval to treat previously treated bladder cancer in May 2016.

Additional Cobimetinib Data Presented at the ESMO 2016 Congress

The poster discussion presentation in advanced melanoma is one of seven cobimetinib abstracts being presented at the ESMO 2016 Congress. Additional data presentations include studies of cobimetinib in combination with other therapies to treat metastatic colorectal cancer and triple-negative breast cancer and BRAF-mutant melanoma. For full logistical information on these other presentations, please see Exelixis' ESMO announcement press release issued on August 31, 2016, available online here.

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 collaboration agreement 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 entitled to an initial equal share of U.S. profits and losses, which will decrease as sales increase, and shares U.S. commercialization costs. In November 2013, Exelixis exercised its option to co-promote cobimetinib in the United States and fields 25 percent of the U.S. sales force, closely coordinating its efforts with Genentech. Outside of the United States, Exelixis is eligible to receive royalties on any sales.

Cobimetinib is now approved in multiple countries, including the United States, European Union, Switzerland, Canada, Australia and Brazil, to treat specific forms of BRAF mutation-positive unresectable or metastatic melanoma, in combination with vemurafenib. The trade name for cobimetinib is COTELLIC®. Further country approvals are anticipated in 2016 and beyond. Cobimetinib is also the subject of a clinical development program aimed at evaluating its potential in combination with a variety of investigational and approved therapies in disease settings including metastatic melanoma, triple-negative breast cancer and advanced solid tumors.

COTELLIC® Indication

COTELLIC (cobimetinib) is a prescription medicine that is used with the medicine Zelboraf® (vemurafenib), to treat a type of skin cancer called melanoma that has spread to other parts of the body or cannot be removed by surgery, and that has a certain type of abnormal “BRAF” gene.

A patient’s healthcare provider will perform a test for the BRAF gene to make sure that COTELLIC is right for them. It is not known if COTELLIC is safe and effective in children under 18 years of age.

COTELLIC® Important Safety Information

Patients should avoid sunlight during treatment with COTELLIC and Zelboraf. COTELLIC and Zelboraf can make a patient’s skin sensitive to sunlight. They may burn more easily and get severe sunburns. When a patient goes outside, they should wear clothes that protect their skin, including their head, face, hands, arms and legs. They should use lip balm and a broad-spectrum sunscreen with SPF 30 or higher.

COTELLIC and Zelboraf may cause serious side effects, including risk of new skin cancers, risk of other cancers, bleeding problems, heart problems, allergic reactions, severe rash and other severe skin reactions, eye problems, changes in the electrical activity of the heart (QT prolongation), liver problems or liver injury, muscle problems (rhabdomyolysis), skin sensitivity to sunlight (photosensitivity), worsening side effects from radiation treatment, and kidney injury.

Patients should tell their doctor if they are pregnant or plan to become pregnant, as COTELLIC and Zelboraf can harm an unborn baby. Females who are able to become pregnant should use effective birth control during treatment with COTELLIC and Zelboraf and for two weeks after the final dose of COTELLIC or Zelboraf (whichever is taken later).

Patients should not breastfeed during treatment and for two weeks after the final dose of COTELLIC or Zelboraf (whichever is taken later). Patients should talk to their healthcare provider about the best way to feed their baby during this time.

Patients should tell their healthcare provider about all the medicines they take. Some types of medicines will affect the blood levels of COTELLIC.

Common side effects of COTELLIC in combination with Zelboraf include diarrhea, sunburn or sun sensitivity, nausea, fever and vomiting. COTELLIC and Zelboraf can also cause changes in blood test results.

Patients should tell their healthcare provider if they have any side effect that bothers them or that does not go away. These are not all the possible side effects of COTELLIC and Zelboraf.

Patients should call their doctor for medical advice about side effects. Patients may report side effects to FDA at (800) FDA-1088 or www.fda.gov/medwatch. Patients may also report side effects to Genentech at (888) 835-2555.

Please see both Full COTELLIC Prescribing Information and Patient Information and Full Zelboraf Prescribing Information and Medication Guide for additional Important Safety Information at www.cotellic.com and www.zelboraf.com.

About Exelixis

Exelixis, Inc. (Nasdaq:EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer. Since its founding in 1994, three medicines discovered at Exelixis have progressed through clinical development to receive regulatory approval. Currently, Exelixis is focused on advancing cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors, which has shown clinical anti-tumor activity in more than 20 forms of cancer and is the subject of a broad clinical development program. Two separate formulations of cabozantinib have received regulatory approval to treat certain forms of kidney and thyroid cancer and are marketed for those purposes as CABOMETYX™ tablets (U.S. and EU) and COMETRIQ® capsules (U.S. and EU), respectively. Another Exelixis-discovered compound, COTELLIC® (cobimetinib), a selective inhibitor of MEK, has been approved in major territories including the United States and European Union, and is being evaluated for further potential indications by Roche and Genentech (a member of the Roche Group) under a collaboration with Exelixis. For more information on Exelixis, please visit www.exelixis.com or follow @ExelixisInc on Twitter.

Forward-Looking Statement Disclaimer

This press release contains forward-looking statements, including, without limitation, statements related to: the presentation of data from a phase 1b clinical trial evaluating the safety and clinical activity of the triple combination of cobimetinib, vemurafenib, atezolizumab at the ESMO 2016 Congress; the clinical and therapeutic potential of adding atezolizumab to the combination regimen of cobimetinib and vemurafenib; the potential for cobimetinib in combination with a variety of investigational and approved therapies in disease settings, including metastatic melanoma, triple-negative breast cancer and advanced solid tumors; the financial terms of Exelixis’ collaboration for cobimetinib with Genentech, including, the plan to share U.S. profits and losses for cobimetinib, and Exelixis’ potential receipt of royalties on sales of cobimetinib products outside the U.S.; further country approvals of cobimetinib in combination with vemurafenib anticipated in 2016 and beyond; Exelixis’ commitment to the discovery, development and

commercialization of new medicines with the potential to improve care and outcomes for people with cancer; Exelixis' focus on advancing cabozantinib; and the continued development of cobimetinib. Words such as "will," "to be," suggest," "promising," "eligible," "anticipated," "potential," "committed," "focused," 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. 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: the availability of data at the referenced times; risks related to the potential failure of cobimetinib to demonstrate safety and efficacy in clinical testing; Exelixis' dependence on its relationship with Genentech/ Roche with respect to cobimetinib and ability to maintain its rights under the collaboration; the degree of market acceptance of and the availability of coverage and reimbursement for COTELLIC; the risk that unanticipated developments could adversely affect the commercialization of COTELLIC; risks related to the potential failure of cabozantinib to demonstrate safety and efficacy in clinical testing; market competition; changes in economic and business conditions; and other factors discussed under the caption "Risk Factors" in Exelixis' annual report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 3, 2016, and in Exelixis' future 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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Source: Exelixis, Inc.

Investors Contact:
Exelixis, Inc.
Susan Hubbard, 650-837-8194
Investor Relations & Public Affairs
shubbard@exelixis.com
or
Media Contact:
For Exelixis, Inc.
Hal Mackins, 415-994-0040
hal@torchcomllc.com