Exelixis Announces Genentech Presentation of Preliminary Phase 1B Trial Results for the Combination of Cobimetinib and Atezolizumab at ASCO 2016 Annual Meeting

June 5, 2016

– Results are the subject of an oral presentation at ASCO 2016 today –

– Phase 3 pivotal trial of combination has been initiated –

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jun. 5, 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 cobimetinib, an Exelixis-discovered MEK inhibitor, in combination with atezolizumab, an anti-PD-L1 antibody discovered and developed by Genentech, in patients with metastatic colorectal cancer (CRC). The results will be the subject of an oral presentation (Abstract #3502) today at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting, which is being held June 3-7 in Chicago, Illinois. Johanna Bendell, M.D., director of the Gastrointestinal Cancer Research Program at the Sarah Cannon Research Institute/Tennessee Oncology, Nashville, Tennessee, will present the results.

"These early data on the combination of cobimetinib, an Exelixis-discovered MEK inhibitor, and atezolizumab, an anti-PD-L1 antibody discovered and developed by Genentech, are encouraging and warrant further study in people with previously-treated metastatic colorectal cancer, including those with microsatellite stable disease," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "Based on these results, Genentech has initiated the COTEZO phase 3 trial in patients with unresectable locally advanced or metastatic colorectal cancer."

This ongoing phase 1b trial includes both a dose escalation stage and dose expansion stage. The trial's primary objective is the evaluation of the safety and tolerability of the combination. Secondary endpoints include objective response rate (ORR) per RECIST, duration of response, progression-free survival (PFS), overall survival (OS), as well as evaluation of biomarkers.

As of the February 12, 2016 data cut-off, 23 patients with advanced CRC (22 with mutant KRAS and one with wild-type KRAS) were enrolled during the trial's escalation and expansion phases. No dose-limiting toxicities were observed. The median follow-up for safety in CRC patients was 3.8 months, with a range of 1.1 to 15.1 months. There were no all-cause grade 5 or treatment-related grade 4 AEs reported, and incidence of treatment-related grade 3 AEs was 35% (n=8). The most common treatment-related AEs, regardless of severity, included: diarrhea (70% of patients); fatigue (52%); dermatitis acneiform (44%); rash (35%); and nausea, maculopapular rash and pruritus (each 26%).

The ORR for the combination was 17%, including four confirmed partial responses; additionally five patients achieved stable disease. The median duration of response was not yet reached, with a range of 5.4 to more than 11.1 months.

Median PFS for all CRC patients enrolled in the trial was 2.3 months, with a range of 1.8 to 9.5 months. The six-month PFS was 35%. Median OS for all CRC patients was not evaluable, while six-month OS was 72%.

Recently Initiated COTEZO Phase 3 Pivotal Trial

In June 2016 Genentech initiated COTEZO, a phase 3 pivotal trial of the combination of cobimetinib and atezolizumab in unresectable locally advanced or metastatic colorectal cancer. The trial is expected to enroll 360 patients who have received at least two prior chemotherapies in the metastatic disease setting. The primary endpoint of the COTEZO trial is overall survival. More information about the COTEZO phase 3 pivotal trial is available at www.clinicaltrials.gov.

Additional Cobimetinib Data Presented at ASCO 2016

The oral presentation in colorectal cancer is one of eight cobimetinib abstracts being presented at the ASCO 2016 Annual Meeting this week. Additional data presentations include studies of cobimetinib in combination with other therapies to treat triple-negative breast cancer and BRAF-mutant melanoma. For full logistical information on these other presentations, please see Exelixis' ASCO announcement press release issued on April 20, 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 resulting from sales of cobimetinib to treat any form of cancer, 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 fielding 25 percent of the U.S. sales force for the product's first commercial indication in specific forms of BRAF mutation-positive advanced melanoma, closely coordinating its efforts with Genentech. Outside of the United States, Exelixis is eligible to receive royalties on any sales.

Cobimetinib in combination with vemurafenib 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 advanced melanoma. 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 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. COTELLIC can make their skin sensitive to sunlight. They may burn more easily and get severe sunburns. To help protect against sunburn, 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 may cause serious side effects, including risk of new skin cancers, bleeding problems, heart problems, severe rash, eye problems, liver problems, muscle problems (rhabdomyolysis), and photosensitivity. Patients should tell their doctor if they are pregnant or plan to become pregnant, as COTELLIC and ZELBORAF can harm an unborn baby. Patients who take COTELLIC should use effective methods of birth control during treatment, for 2 weeks after stopping COTELLIC, and for at least 2 months after stopping ZELBORAF. Do not breastfeed during treatment with COTELLIC and for 2 weeks after the final dose. Patients along with their healthcare provider should decide if they will take ZELBORAF or breastfeed. Patients should not do both.

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 include diarrhea, sunburn or sun sensitivity, nausea, fever, and vomiting. COTELLIC 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. For more information about side effects, patients should ask their healthcare provider or pharmacist.

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

Please see full COTELLIC Prescribing Information and Patient Information for additional Important Safety Information.

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 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 cobimetinib in combination with atezolizumab in CRC and other cobimetinib data presentations at the 2016 ASCO Annual Meeting; expectations regarding enrollment of COTEZO; 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," "eligible," "anticipated," "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 and atezolizumab 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; 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 May 4, 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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