Exelixis Announces Presentation of Cobimetinib Combination Therapy Data at the Society for Melanoma Research 2016 Congress That Support Genentech's Planned Phase 3 Pivotal Trials

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- Encouraging data in BRAF wild type advanced melanoma presented in advance of initiation of phase 3 pivotal trial next year -

- The third pivotal phase 3 trial of cobimetinib announced this year, reflecting robust late-stage development program -

SOUTH SAN FRANCISCO, Calif. & BOSTON--(BUSINESS WIRE)--Nov. 7, 2016-- Exelixis, Inc. (NASDAQ:EXEL) today announced the presentation of new data from clinical trials of cobimetinib in combination with other therapies to treat forms of advanced melanoma. Data from phase 1b trials of cobimetinib in combination with atezolizumab, and with atezolizumab and vemurafenib, respectively, form the basis for two Genentech-sponsored phase 3 pivotal trials anticipated to start in 2017. Additionally, data from a pooled analysis of the combination of cobimetinib and vemurafenib demonstrate the potential for the combination to deliver lasting clinical benefit.

The data are being presented at the Society for Melanoma Research 2016 Congress, which is being held November 6-9 in Boston. Cobimetinib, a selective MEK inhibitor discovered by Exelixis and now the subject of a worldwide collaboration agreement with Genentech, a member of the Roche Group, is the subject of seven abstracts at the meeting.

"Since its initial regulatory approval last year, cobimetinib has continued to generate encouraging data with the potential to broaden its utility as a key component of combination regimens to treat serious forms of cancer," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "If confirmed in the pivotal trials planned to initiate next year, the cobimetinib/atezolizumab and triple-combination regimens described in data at this year's Society for Melanoma Research Congress could become important new therapeutic options for clinicians treating multiple forms of advanced melanoma."

Pivotal Trial in BRAF Wild-Type Melanoma Planned Following Encouraging Phase 1b Data

In a plenary session at the SMR 2016 Congress today, Jeffrey R. Infante, M.D., Director of the Drug Development Program and Principal Investigator at Sarah Cannon Research Institute, Nashville, Tennessee will present results from the metastatic melanoma cohort of a phase 1b dose escalation trial of cobimetinib and atezolizumab, an anti-PDL1 antibody developed by Genentech, in patients with solid tumors. The primary objective of the trial is to determine the safety and clinical activity of the combination, and key eligibility criteria include ECOG Performance Status of 0 or 1, measurable disease per RECIST, and no prior anti-PD-1/PDL1 therapy.

As of the July 12, 2016 data cut-off, 22 patients with metastatic melanoma were evaluable for safety and efficacy, including 20 patients with non-ocular melanoma (10 each with BRAF wild type and BRAF V600-mutation positive disease) and two patients with ocular melanoma. Among the 20 non-ocular melanoma patients, the objective response rate (ORR) was 45 percent, with 9 partial responses, including 5 in BRAF wild-type patients. Median duration of response was 14.9 months (12.9, upper limit not yet reached) across 9 responders, and was not yet reached for the BRAF wild-type subgroup. Median progression-free survival (PFS) was 12 months across all non-ocular melanoma patients (15.7 months in BRAF wild-type and 11.9 months in BRAF mutation-positive patients). With a median follow-up of 18.9 months, median overall survival (OS) for the cohort had not been reached.

All patients in the cohort were evaluable for safety. In this phase 1b study, investigators reported the combination of cobimetinib and atezolizumab was generally well tolerated. Treatment-related Grade 3-4 adverse events (AEs) occurred in 59 percent of patients, and no treatment-related grade 5 AEs were reported.

Based on these results, Genentech plans to initiate a phase 3 pivotal trial of cobimetinib plus atezolizumab versus a PD-1 inhibitor in patients with previously untreated BRAF wild-type advanced melanoma next year. More information on the planned study will be posted to www.ClinicalTrials.gov when available.

Updated Results for Triple Combination of Cobimetinib, Vemurafenib and Atezolizumab Set Stage for TRILOGY Pivotal Trial

Also in a plenary session today, Ryan Sullivan, M.D., Instructor in Medicine at Harvard Medical School and Member of the Cancer Immunology and Melanoma Programs at Dana-Farber Cancer Institute will present results from the phase 1b trial of cobimetinib, vemurafenib and atezolizumab in patients with BRAF V600 mutation-positive metastatic melanoma. The primary objective of the trial is evaluation of the safety and tolerability of the triple combination, with secondary endpoints including PFS, OS, ORR, best overall response, and duration of response, among others.

Patients in the trial receive the triple combination of cobimetinib, vemurafenib and atezolizumab following a 28-day run-in cycle of cobimetinib plus vemurafenib. As of the June 15, 2016 data cut-off, 30 patients with previously untreated BRAF V600 mutation-positive advanced melanoma who received at least one dose of atezolizumab were evaluable for safety and efficacy. Responses were seen in 24 of 29 patients (83 percent) evaluable for efficacy, including three complete responses and 21 partial responses. Median duration of response and median PFS were not estimable due to limited follow-up time; the majority of patients continued to respond at time of data cut-off (median follow-up of 5.6 months).

Investigators reported the triple combination of cobimetinib, vemurafenib and atezolizumab was generally well tolerated in this investigational study. Median safety follow-up was 3.9 months (range 0.7-16.8 months). Grade 3-4 AEs were seen in 40 percent of patients that received the triple combination, and all AEs resolved after appropriate intervention. No unexpected AEs, grade 5 AEs or atezolizumab-related serious AEs occurred.

In early 2017, Genentech and Roche plan to initiate TRILOGY (NCT02908672), a pivotal placebo-controlled phase 3 trial evaluating the combination of cobimetinib, vemurafenib and atezolizumab compared to cobimetinib, vemurafenib and placebo. TRILOGY will enroll an estimated 500 patients with

previously untreated BRAF V600 mutation-positive metastatic melanoma. The primary endpoint of TRILOGY is PFS as determined by the investigator, and secondary endpoints include PFS by independent review committee, OS, ORR, duration of response, safety and pharmacokinetics. For more information, visit www.ClinicalTrials.gov.

Efficacy of Long-Term Cobimetinib and Vemurafenib Detailed in Poster Session

Also at the SMR 2016 Congress, Prof. Grant McArthur, Co-chair of the Melanoma and Skin Service at Peter MacCallum Cancer Centre (Melbourne, Victoria, Australia) and colleagues presented a poster demonstrating the continuing benefit across all patient subgroups of the combination therapy of cobimetinib and vemurafenib versus vemurafenib monotherapy as assessed in the coBRIM phase 3 pivotal trial that formed the basis for the combination's regulatory approval to treat BRAF V600-mutation positive advanced melanoma. The percentage of patients alive at three years was 37.4 percent for cobimetinib and vemurafenib, as compared to 31.1 percent for patients treated with vemurafenib plus placebo. Median overall survival was 22.5 months for the combination versus 17.4 months for vemurafenib alone. The safety profile was similar to what was reported previously, and discontinuation rates due to AEs were below 20 percent.

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 colorectal carcinoma.

About Advanced Melanoma

Melanoma is less common, but more aggressive and deadlier than other forms of skin cancer. When melanoma is diagnosed early, it is generally a curable disease, but most people with advanced melanoma have a poor prognosis. The American Cancer Society estimates there will be nearly 74,000 new cases of melanoma and 10,000 melanoma deaths this year in the United States.

In recent years, there have been significant advances in treatment for advanced 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.

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 potential for the combination of cobimetinib and vemurafenib to deliver lasting clinical benefit; the potential for the cobimetinib/atezolizumab and triple-combination regimens described in data at this year's Society for Melanoma Research Congress to become important new therapeutic options for clinicians treating multiple forms of advanced melanoma; the presentation of data from the metastatic melanoma cohort of a phase 1b dose escalation trial of cobimetinib and atezolizumab; Genentech's plan to initiate a phase 3 pivotal trial of cobimetinib plus atezolizumab versus a PD-1 inhibitor in patients with previously untreated BRAF wild-type advanced melanoma next year; the presentation of data from the phase 1b trial of cobimetinib, vemurafenib and atezolizumab in patients with BRAF V600 mutation-positive metastatic melanoma; Genentech's and Roche's plan to initiate TRILOGY in early 2017 and expectations regarding the trial's enrollment; 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 to treat BRAF mutation-positive unresectable or metastatic melanoma anticipated in 2016 and beyond; 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 colorectal carcinoma; estimates regarding new cases of melanoma and melanoma deaths in the United States; 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 "next," "anticipated," "potential," "could," "plans," "expected," "will," "eligible," "estimates," "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 November 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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