Exelixis Announces Settlement of Dispute with Genentech Regarding Companies' Collaboration Agreement for Cobimetinib

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- Companies define new revenue and cost-sharing terms for all commercial applications of cobimetinib -

- Cobimetinib's clinical development program includes three ongoing or planned phase 3 pivotal trials -

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 20, 2017-- Exelixis, Inc. (NASDAQ:EXEL) announced today a settlement of the company's dispute with Genentech, a member of the Roche Group, concerning the parties' collaboration for the development and commercialization of cobimetinib, which is marketed as COTELLIC®. Effective July 1, 2017, as part of the settlement the companies entered into an amendment (the "Amendment") to the existing Collaboration Agreement, dated December 22, 2006, to revise the revenue and cost-sharing arrangements for the collaboration. The Amendment resolves the companies' dispute pursuant to the arbitration demand filed on June 3, 2016, and aligns both companies' interests in advancing cobimetinib as a promising therapy for patients with multiple forms of cancer.

The Amendment applies to COTELLIC®s initial commercial application in combination with ZELBORAF ® (vemurafenib), as well as future commercial uses of COTELLIC®, alone or in combination. Under its terms, Exelixis continues to be entitled to an initial equal share of U.S. profits and losses, which will decrease as sales increase as specified in the original 2006 agreement. However, effective as of July 1, 2017, the revenue applied to the profit and loss statement for the COTELLIC® collaboration ("the Collaboration P&L") will be calculated using the average of the quarterly net selling prices of COTELLIC® and any additional branded Genentech product(s) prescribed with COTELLIC®. Exelixis will continue to share U.S. commercialization costs, while Genentech's portion of these costs will now be allocated to the Collaboration P&L based on the number of products in the combination. Exelixis will continue to co-promote COTELLIC® in the U.S., providing up to 25 percent of the U.S. sales force. Outside of the U.S., Exelixis remains eligible for royalties on COTELLIC® sales according to the terms of the original 2006 agreement.

"The settlement and revised revenue and commercial cost-sharing arrangements lay the groundwork for our continued work together to maximize cobimetinib's potential to help patients," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "Since signing our collaboration agreement with Genentech more than ten years ago, cobimetinib has advanced from our discovery and early clinical efforts into Genentech's global clinical development organization – where it is now the subject of three ongoing or planned pivotal trials – and into commercial use around the world. With this new framework in place, we look forward to continuing our collaborative efforts with Genentech to maximize this promising medicine's impact on the treatment of cancer."

Genentech has been responsible for cobimetinib's clinical development since it opted to further develop the compound following Exelixis' determination of a maximum tolerated dose in phase 1 clinical trials. Since then, Genentech has undertaken a clinical development program focused on evaluating cobimetinib's potential in combination with investigational and approved therapies. This program includes three phase 3 pivotal trials: IMblaze370, an ongoing and fully enrolled study evaluating cobimetinib and atezolizumab in third-line advanced or metastatic colorectal cancer; IMspire150 TRILOGY, an ongoing trial evaluating the combination of cobimetinib, atezolizumab and vemurafenib in patients with previously untreated BRAF V600 mutation-positive metastatic or unresectable locally advanced melanoma; and IMspire170, a planned study evaluating cobimetinib plus atezolizumab in patients with previously untreated BRAF wild-type metastatic or unresectable locally advanced melanoma expected to start in the third quarter of this year.

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 U.S., 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®. 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.

Important: If a patient's healthcare provider prescribes ZELBORAF ® (vemurafenib), the patient should also read the Medication Guide that comes with ZELBORAF®.

COTELLIC® Indication

COTELLIC® is a prescription medicine that is used with the medicine ZELBORAF® 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 to make sure that COTELLIC ® is right for the patient. It is not known if COTELLIC® is safe and effective in children under 18 years of age.

Important Safety Information

Before taking COTELLIC®, patients should tell their healthcare provider about all of their medical conditions, including if they:

- have skin problems or history of skin problems, other than melanoma
- have bleeding problems, any medical conditions and/or on any medications that increase the risk of bleeding
- have heart problems
- have eye problems
- have liver problems
- have muscle problems
- are pregnant or plan to become pregnant. 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 for two weeks after the final dose of COTELLIC®.
    - Patients should talk to their healthcare provider about birth control methods that may be right for them.
    - Patients should tell their healthcare provider right away if they become pregnant or think they are pregnant during treatment with COTELLIC® and ZELBORAF®.
- are breastfeeding or plan to breastfeed. It is not known if COTELLIC® passes into breast milk. Patients should not breastfeed during treatment with COTELLIC® and for two weeks after the final dose. 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, including prescription and over-the-counter medicines, vitamins and herbal supplements. Certain medicines may affect the blood levels of COTELLIC®.

Patients should know the medicines they take and keep a list of them to show their healthcare provider and pharmacist when they get a new medicine.

How should patients take COTELLIC®?

- Patients should take COTELLIC® exactly as their healthcare provider tells them. Patients should not change their dose or stop taking COTELLIC® unless their healthcare provider tells them to.
- Patients should take COTELLIC® one time a day for 21 days, followed by seven days off treatment, to complete a 28-day treatment cycle.
- Patients can take COTELLIC® with or without food.
- If a patient misses a dose of COTELLIC® or vomits after taking their dose, they should take their next dose as scheduled.

What should patients avoid during treatment with COTELLIC®?

Patients should avoid sunlight during treatment with COTELLIC®. COTELLIC® can make a patient’s skin sensitive to sunlight. They may burn more easily and get severe sunburns. To help protect against sunburn:

- 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.

What are the possible side effects of COTELLIC®?

COTELLIC® may cause serious side effects, including:

- **Risk of new skin cancers.** COTELLIC® may cause new skin cancers (cutaneous squamous cell carcinoma, keratoacanthoma or basal cell carcinoma).

Patients should check their skin regularly and tell their healthcare provider right away if they have any skin changes including:

- new wart
- skin sore or reddish bump that bleeds or does not heal
- change in size or color of a mole

A patient's healthcare provider should check the patient's skin before they start taking COTELLIC ®, and every two months during treatment with COTELLIC®. A patient's healthcare provider may continue to check the patient's skin for six months after the patient stops taking COTELLIC ®. A patient's healthcare provider should also check for cancers that may not occur on the skin. Patients should tell their healthcare provider about any new symptoms that develop during treatment with COTELLIC®.

- **Bleeding problems.** COTELLIC® can cause serious bleeding problems.

Patients should call their healthcare provider and get medical attention right away if they get any signs of bleeding, including:

• red or black stools (looks like tar)
• stomach (abdominal) pain
• blood in their urine
• unusual vaginal bleeding
• headaches
• dizziness or weakness
• cough up or vomit blood

- **Heart problems.** A patient's healthcare provider should do tests before and during treatment to check the patient's heart function. Patients should tell their healthcare provider if they get any of these signs and symptoms of heart problems:

• persistent coughing or wheezing
• tiredness
• shortness of breath
• increased heart rate
• swelling of their ankles and feet

- **Severe rash.** Patients should tell their healthcare provider right away if they get any of these symptoms:

• a rash that covers a large area of their body
• blisters
• peeling skin

- **Eye problems.** Patients should tell their healthcare provider right away if they get any of these symptoms:

• blurred vision
• see halos
• partly missing vision or loss of vision
• any other vision changes

A patient's healthcare provider should check the patient's eyes if the patient notices any of the symptoms above.

- **Liver problems.** A patient's healthcare provider should do blood tests to check the patient's liver function before and during treatment. Patients should tell their healthcare provider right away if they get any of these symptoms:

• yellowing of their skin or the white of their eyes
• feeling tired or weak
• dark or brown (tea color) urine
• loss of appetite
• nausea or vomiting

- **Muscle problems (rhabdomyolysis).** COTELLIC® can cause muscle problems that can be severe. Treatment with COTELLIC® may increase the level of an enzyme in the blood called creatine phosphokinase (CPK) and may be a sign of

muscle damage. A patient's healthcare provider should do a blood test to check the patient's levels of CPK before and during treatment. Patients should tell their healthcare provider right away if they get any of these symptoms:

• muscle aches or pain • dark, reddish urine

• muscle spasms and weakness

- **Skin sensitivity to sunlight (photosensitivity)**. Skin sensitivity to sunlight during treatment with COTELLIC® is common and can sometimes be severe. Patients should tell their healthcare provider if they get any of these symptoms:

• red, painful, itchy skin that is hot to touch • bumps or tiny papules

• sun rash • thickened, dry, wrinkled skin

• skin irritation

See "What should patients avoid during treatment with COTELLIC®?" for information on protecting the skin during treatment with COTELLIC®.

The most common side effects of COTELLIC® include:

• diarrhea • vomiting

• nausea • sunburn or sun sensitivity

• fever

A patient's healthcare provider will take blood tests during treatment with COTELLIC ®. The most common changes to blood tests include:

- increased blood levels of liver enzymes (GGT, ALT or AST)
- increased blood level of enzyme from muscle (creatine phosphokinase)
- decreased blood level of phosphate, sodium or potassium
- increased blood level of liver or bone enzyme (alkaline phosphatase)
- decreased blood level of a type of white blood cell (lymphocyte)

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®.

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 Full COTELLIC® Prescribing Information and Patient Information for additional Important Safety Information at www.cotellic.com.

About Exelixis

Exelixis, Inc. (Nasdaq: EXEL) is a biopharmaceutical company committed to the discovery, development and commercialization of new medicines to improve care and outcomes for people with cancer. Since its founding in 1994, three products discovered at Exelixis have progressed through clinical development, received regulatory approval, and entered the marketplace. Two are derived from cabozantinib, an inhibitor of multiple tyrosine kinases including MET, AXL and VEGF receptors: CABOMETYX ™ tablets approved for previously treated advanced kidney cancer and COMETRIQ® capsules approved for progressive, metastatic medullary thyroid cancer. The third product, COTELLIC®, is a formulation of cobimetinib, a reversible inhibitor of MEK, is marketed under a collaboration with Genentech (a member of the Roche Group), and is approved as part of a combination regimen to treat advanced melanoma. Both cabozantinib and cobimetinib have shown potential in a variety of forms of cancer and are the subjects of broad clinical development programs. 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 therapeutic potential and continued development of cobimetinib; ongoing activities under the Collaboration Agreement; Exelixis continuing to be entitled to a share of U.S. profits and

losses received in connection with commercialization of COTELLIC® and eligible to receive royalties on sales of COTELLIC® outside the U.S.; the potential for increased COTELLIC® sales; Genentech's plan to start IMspire170 in the third quarter of this year; Exelixis' commitment to the discovery, development and commercialization of new medicines to improve care and outcomes for people with cancer; and the therapeutic potential and continued development of cabozantinib. Words such as "promising," "will," "eligible," "potential," "look forward," "planned," "committed," 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: Exelixis' dependence on its relationship with Genentech with respect to COTELLIC® and ability to maintain its rights under the Collaboration Agreement; the risk that unanticipated developments could adversely affect the commercialization of COTELLIC® and/or the parties' willingness to perform their respective obligations under the Collaboration Agreement; the degree of market acceptance of COTELLIC® and the availability of coverage and reimbursement for COTELLIC®; Genentech's ability to conduct clinical trials of COTELLIC ® sufficient to achieve a positive completion; risks related to the potential failure of COTELLIC® to demonstrate safety and efficacy in clinical testing; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; 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' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on May 1, 2017, 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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