Exelixis' Cabozantinib Granted Orphan Drug Designation for the Treatment of Hepatocellular Carcinoma

March 6, 2017

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Mar. 6, 2017-- Exelixis, Inc. (Nasdaq: EXEL) today announced that the U.S. Food & Drug Administration (FDA) has granted orphan drug designation to cabozantinib for the treatment of hepatocellular carcinoma (HCC). This information was posted to FDA's website on March 4, 2017 and can be accessed at

http://www.accessdata.fda.gov/scripts/opdlisting/oopd/detailedIndex.cfm?cfgridkey=552916

A pivotal phase 3 trial (CELESTIAL) of cabozantinib is ongoing in patients with advanced HCC, and Exelixis has guided that data from the trial are expected in 2017.

Orphan drug status is granted to treatments for diseases that affect fewer than 200,000 people in the U.S. and provides certain incentives for medications intended for the treatment, diagnosis or prevention of rare diseases. At present, these incentives include seven years of marketing exclusivity for the orphan indication, certain federal grants, tax credits and waiver of certain FDA fees.

About the CELESTIAL Trial

CELESTIAL is designed to enroll 760 patients with advanced HCC who received prior sorafenib. Patients are randomized 2:1 to receive 60 mg of cabozantinib daily or placebo. The primary endpoint for the trial is overall survival, and secondary endpoints include objective response rate and progression-free survival. Exploratory endpoints include patient-reported outcomes, biomarkers and safety. The CELESTIAL trial is being conducted at more than 100 sites globally in 19 countries.

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 selective 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 Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the expectation for CELESTIAL data results in 2017; Exelixis' commitment to the discovery, development and commercialization of new medicines with the potential to improve care and outcomes for people with cancer; the clinical potential of cabozantinib and cobimetinib in a variety of forms of cancer; and the continued development of cabozantinib and cobimetinib. Words such as "guided," "expected," "committed," "potential," 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 time; 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; risks and uncertainties related to regulatory review and approval processes and Exelixis' compliance with applicable legal and regulatory requirements; the degree of market acceptance of CABOMETYX and COMETRIQ; Exelixis' dependence on its relationship with its cabozantinib collaboration partners, including, the level of their investment in the resources necessary to successfully commercialize cabozantinib in the territories where it is approved; Exelixis' dependence on its relationship with Genentech/Roche with respect to cobimetinib and Exelixis' ability to maintain its rights under the collaboration; Exelixis' dependence on third-party vendors; Exelixis' ability to protect the company's intellectual property rights; market competition; changes in economic and business conditions, and other factors discussed under the caption "Risk Factors" in Exelixis' annual report on Form 10-K filed with the Securities and Exchange Commission (SEC) on February 27, 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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