Exelixis Announces Collaborator Daiichi Sankyo's Submission of Regulatory Filing for Esaxerenone (CS-3150) in Japan

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– Filing triggers $20 million milestone payment to Exelixis –

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Feb. 26, 2018-- Exelixis, Inc. (NASDAQ: EXEL) today announced that its partner Daiichi Sankyo Company, Limited ("Daiichi Sankyo") has submitted its regulatory application for esaxerenone (INN; code name CS-3150) as a treatment for patients with hypertension to the Japanese Pharmaceutical and Medical Devices Agency. Esaxerenone is a compound identified during the prior research collaboration between Exelixis and Daiichi Sankyo, and has been subsequently developed by Daiichi Sankyo. As a result of the submission, Exelixis will receive a $20 million milestone payment per the two companies' collaboration agreement.

Daiichi Sankyo's application is based on the results of phase 3 studies including ESAX-HTN, a randomized, double-blind, three-arm parallel group comparison study evaluating the efficacy and safety of esaxerenone versus eplerenone in patients with essential hypertension in Japan. Top-line results for ESAX-HTN were announced in September 2017, and Daiichi Sankyo plans to disclose detailed study results at a future scientific meeting.

"Daiichi Sankyo has been an excellent partner throughout the years, and continues to be effective in its clinical and regulatory progress. Daiichi Sankyo's regulatory filing for esaxerenone is an important step toward a potential new therapeutic option for patients with hypertension in Japan, where more than 43 million people are estimated to have high blood pressure," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "This milestone is another example of the critical role our partnered compounds can play by generating additional revenues for us to reinvest in our business as we work to bring new medicines to market for difficult-to-treat cancers."

In March 2006, Daiichi Sankyo and Exelixis entered into a research collaboration agreement to discover, develop and commercialize novel therapies targeting the mineralocorticoid receptor (MR). Under the terms of the agreement, Daiichi Sankyo has exclusive global development, manufacturing and commercialization rights for the compounds. Esaxerenone, a non-steroidal, selective novel MR blocker, is one of the compounds identified during the research collaboration, and has subsequently been developed by Daiichi Sankyo. As esaxerenone advances, Exelixis is eligible for substantial commercialization milestones, as well as double-digit royalties on sales.

About Hypertension in Japan

According to the 2012 Japan National Health and Nutrition Survey, there are an estimated 43 million patients with hypertension in the country, which accounts for 60% of men and 45% of women over the age of 30 in the general Japanese population.[1] Only approximately 30% of men and 40% of women with hypertension who are treated with antihypertensive medication typically achieve the goal of systolic and diastolic blood pressure lower than 140/90mm Hg.

Hypertension is one of the major risk factors for cardiovascular disease, such as stroke and coronary heart disease, and the condition also raises the risk of chronic kidney disease and end-stage renal disease.[1] Essential hypertension is the most common form of hypertension, affecting 90% of hypertensive patients, and is associated with heterogeneous contributory factors such as genetics and lifestyle habits, while secondary hypertension is associated with identified underlying disease factors.[1]

About Esaxerenone (CS-3150)

Esaxerenone is an oral, non-steroidal, selective blocker of the mineralocorticoid receptor (MR), a nuclear hormone receptor implicated in a variety of cardiovascular and metabolic diseases. MR blockers can be used to treat hypertension and congestive heart failure due to their vascular protective effects. Recent studies have also suggested beneficial effects of adding MR blockers to the treatment regimen for Type 2 diabetic patients with nephropathy. As a non-steroidal, selective MR blocker, esaxerenone may have potential for the treatment of hypertension, diabetic nephropathy and congestive heart failure, and may provide protection from end organ damage due to vascular complications.

Esaxerenone is one of the compounds identified during Exelixis' research collaboration with Daiichi Sankyo, which the companies entered into in March 2006. Under the terms of the agreement, Exelixis granted Daiichi Sankyo an exclusive, worldwide license to certain intellectual property primarily relating to compounds that modulate MR. In exchange, Exelixis received a $20 million upfront payment, research funding for a joint research period, and the potential for substantial clinical development, regulatory and commercialization milestone payments, as well as double-digit royalties on sales. Since the conclusion of the joint research period in November 2007, Daiichi Sankyo has been responsible for all subsequent preclinical and clinical development, and will also oversee regulatory, manufacturing and commercialization activities for the compound.

About Exelixis

Founded in 1994, Exelixis, Inc. (NASDAQ: EXEL) is a commercially successful, oncology-focused biotechnology company that strives to accelerate the discovery, development and commercialization of new medicines for difficult-to-treat cancers. Following early work in model genetic systems, we established a broad drug discovery and development platform that has served as the foundation for our continued efforts to bring new cancer therapies to patients in need. We discovered our lead compounds, cabozantinib and cobimetinib, and advanced them into clinical development before

entering into partnerships with leading biopharmaceutical companies in our efforts to bring these medicines to patients globally. We are steadfast in our commitment to prudently reinvest in our business to maximize the potential of our pipeline. We intend to supplement our existing therapeutic assets with targeted business development activities and internal drug discovery – all to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Exelixis recently earned a spot on Deloitte's Technology Fast 500 list, a yearly award program honoring the 500 fastest-growing companies over the past four years. For more information about 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: Daiichi Sankyo's payment of a $20 million milestone to Exelixis in connection with its submission of a regulatory application in Japan for esaxerenone; Daiichi Sankyo's intention to present ESAX-HTN results at a future scientific meeting; esaxerenone's potential as a new therapeutic option for patients with hypertension, diabetic nephropathy and congestive heart failure, and its ability to provide protection from end organ damage due to vascular complications; the potential for esaxerenone to meaningfully contribute to Exelixis' business and directly support the development of future Exelixis medicines; Exelixis' eligibility for future commercialization milestones, plus royalties on sales under its collaboration with Daiichi Sankyo; Exelixis' mission of helping cancer patients recover stronger and live longer; growing revenues from Exelixis' products and plans to reinvest in its business to maximize the potential of the company's pipeline, including through targeted business development activities and internal drug discovery; and Exelixis' mission to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Words such as "will", plans," "can", eligible," "future," "intention," "potential," "mission," "may," 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: risks and uncertainties related to regulatory review and approval processes; Exelixis' dependence on its relationship with Daiichi Sankyo with respect to esaxerenone, including the level of Daiichi Sankyo's investment in the resources necessary to successfully commercialize esaxerenone in territories where it is ultimately approved; market acceptance of CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib), and COTELLIC® (cobimetinib) and the availability of coverage and reimbursement for these products; the availability of data at the referenced times; the risk that unanticipated developments could adversely affect the commercialization of CABOMETYX, COMETRIQ, and COTELLIC; the level of costs associated with Exelixis' commercialization, research and development and other activities; 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 26, 2018, 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.

References:

[1] The Japanese Society of Hypertension Guidelines for the Management of Hypertension (JSH 2014). Hypertens Research 2014; 37: 253-392.

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