Exelixis' Collaborator Daiichi Sankyo Launches MINNEBRO® (Esaxerenone) Tablets in Japan

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-- First commercial sale triggers $20 million milestone payment to Exelixis --

ALAMEDA, Calif.--(BUSINESS WIRE)--May 13, 2019-- Exelixis, Inc. (Nasdaq: EXEL) today announced its partner Daiichi Sankyo Company, Limited ("Daiichi Sankyo") has launched MINNEBRO ® (esaxerenone) tablets as a treatment for patients with hypertension in Japan. With Daiichi Sankyo's first commercial sale of MINNEBRO, Exelixis will receive an associated $20 million milestone payment from Daiichi Sankyo under the terms of the companies' collaboration agreement. Exelixis anticipates receiving the payment during the second quarter of 2019.

"Daiichi Sankyo's launch of MINNEBRO in Japan is an important advance for patients with hypertension in Japan, as well as for our two companies," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "We congratulate Daiichi Sankyo on this milestone and look forward to the company's further progress in MINNEBRO's clinical development and commercialization."

MINNEBRO is a novel mineralocorticoid receptor blocker identified during the prior research collaboration between Exelixis and Daiichi Sankyo and subsequently developed and commercialized by Daiichi Sankyo. The companies entered into their research collaboration in March 2006. MINNEBRO's regulatory application acceptance in Japan in the first quarter of 2018 triggered a previous $20 million milestone payment, and Exelixis remains eligible for substantial commercialization milestones, as well as low double-digit royalties on MINNEBRO sales. Daiichi Sankyo is also conducting an ongoing phase 3 trial of esaxerenone in patients with diabetic nephropathy in Japan (ESAX-DN).

About MINNEBRO® (Esaxerenone) Tablets

MINNEBRO® (Esaxerenone) tablets (1.25 mg, 2.5 mg and 5 mg) are approved by the Japanese Ministry of Health, Labour, and Welfare as a treatment for patients with hypertension in Japan. The application for approval was submitted in Japan in February 2018 on the basis of results that included data from a phase 3 clinical trial conducted in Japan (ESAX-HTN study) in patients with essential hypertension. Excessive mineralocorticoid receptor (MR) activation has been found to be involved in hypertension, and MINNEBRO is considered to exert an antihypertensive effect by blocking this receptor activation.

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 percent of men and 45 percent of women over the age of 30 in the general Japanese population.[1] Only approximately 30 percent of men and 40 percent 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 percent 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 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. Our discovery efforts have resulted in four marketed products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib), COTELLIC® (cobimetinib) and MINNEBRO® (esaxerenone), and we have entered into partnerships with leading pharmaceutical companies to bring these important medicines to patients worldwide. Supported by revenues from our marketed products and collaborations, we are committed to prudently reinvesting in our business to maximize the potential of our pipeline. We are supplementing 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 is a member of Standard & Poor's (S&P) MidCap 400 index, which measures the performance of profitable mid-sized companies. For more information about Exelixis, please visit www.exelixis.com, follow @ExelixisInc on Twitter or like Exelixis, Inc. on Facebook.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the anticipated timing for receipt of a $20 million milestone payment from Daiichi Sankyo associated with the first commercial sale of MINNEBRO in Japan; the potential for further progress in MINNEBRO's clinical development and commercialization; Exelixis' eligibility for substantial commercialization milestones as well as low double-digit royalties on the sale of MINNEBRO; and Exelixis' 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. Any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements and 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 degree of market acceptance of MINNEBRO in the territories where it is approved, and Daiichi Sankyo's ability to obtain or maintain coverage and reimbursement for this product; Exelixis' dependence on its relationship with Daiichi Sankyo, including Daiichi Sankyo's investment in the resources necessary to successfully commercialize MINNEBRO in the territories where it is approved; market competition, including the potential for competitors to obtain approval for generic versions of MINNEBRO; Exelixis' and Daiichi Sankyo's continuing compliance with applicable legal and regulatory requirements; Exelixis' and Daiichi Sankyo's ability to protect their respective intellectual property rights; changes in economic and business conditions; and other factors affecting Exelixis and its partnerships 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, 2019, and in Exelixis' future filings with the SEC. All forward-looking statements in this press release are based on information available to Exelixis as of the date of this press release, and Exelixis undertakes no obligation to update or revise any forward-looking statements contained herein.

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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Source: Exelixis, Inc.

Investors Contact:
Susan Hubbard
EVP, Public Affairs & Investor Relations
Exelixis, Inc.
650-837-8194
shubbard@exelixis.com

Media Contact:
Hal Mackins
For Exelixis, Inc.
415-994-0040
hal@torchcommunications.com