Exelixis' Collaborator Daiichi Sankyo Receives Regulatory Approval For MINNEBRO™ (Esaxerenone) Tablets for the Treatment of Hypertension in Japan

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ALAMEDA, Calif.--(BUSINESS WIRE)--Jan. 8, 2019-- Exelixis, Inc. (Nasdaq: EXEL) today announced that its partner Daiichi Sankyo Company, Limited ("Daiichi Sankyo") received approval from the Japanese Ministry of Health, Labour and Welfare (MHLW) for esaxerenone tablets, MINNEBRO™ 1.25 mg, 2.5 mg, and 5 mg, as a treatment for patients with hypertension. This approval allows for the marketing of MINNEBRO for this indication within Japan. MINNEBRO is a compound identified during the prior research collaboration between Exelixis and Daiichi Sankyo, which the companies entered into in March 2006, and has been subsequently developed by Daiichi Sankyo.

"The approval of MINNEBRO brings an important new therapeutic option to clinicians in Japan. It also marks a significant scientific milestone for Exelixis, joining cabozantinib and cobimetinib as the third molecule from our discovery efforts to receive regulatory approval," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "We congratulate our partner Daiichi Sankyo on their superb clinical development program and recent approval. As partnered compounds like MINNEBRO are commercialized, we are committed to using resulting collaboration revenues to reinvest in our business, build our pipeline, and pursue long-term, sustainable growth."

Per the collaboration agreement between Exelixis and Daiichi Sankyo, Exelixis will receive a $20 million milestone payment upon the first commercial sale of MINNEBRO in Japan. Exelixis previously received a $20 million milestone payment in the first quarter of 2018 triggered by the filing of Daiichi Sankyo's associated regulatory application. Exelixis is eligible for substantial commercialization milestones, as well as low double-digit royalties on sales of MINNEBRO. Since the conclusion of Exelixis and Daiichi Sankyo's joint research period in November 2007, Daiichi Sankyo has been responsible for all subsequent preclinical and clinical development, and also oversees regulatory, manufacturing and commercialization activities for MINNEBRO.

The MINNEBRO approval was 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, with a primary endpoint of sitting systolic blood pressure (SBP) / diastolic blood pressure (DBP) change from baseline after 12 weeks of treatment. Daiichi Sankyo is also evaluating the compound's effectiveness in Japanese patients with diabetic nephropathy in the ongoing phase 3 pivotal ESAX-DN study.

The MINNEBRO approval comes as Exelixis builds out its pipeline behind CABOMETYX, its lead medicine, through targeted in-licensing and a return to internal drug discovery. Prior to its decision to focus on clinical development in 2010, Exelixis researchers discovered the compounds that would become the company's marketed medicines, COMETRIQ, CABOMETYX and COTELLIC, and filed multiple INDs per year. During this same time period, the company entered into the research collaboration with Daiichi Sankyo that led to MINNEBRO.

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 including a phase 3 clinical trial conducted in Japan (ESAX-HTN study) in patients with essential hypertension. Excessive mineralocorticoid receptor 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. We discovered our three commercially available products, CABOMETYX® (cabozantinib), COMETRIQ® (cabozantinib) and COTELLIC® (cobimetinib), and 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 the second consecutive year, Exelixis 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, follow @ExelixisInc on Twitter or like ExelixisInc on Facebook.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: Exelixis' timing for receipt of a $20 million milestone payment from Daiichi Sankyo upon the first commercial sale of MINNEBRO in Japan; the potential of MINNEBRO as a new therapeutic option for clinicians in Japan; Exelixis' eligibility for substantial commercialization milestones as well as 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; Exelixis' dependence on its relationships with Daiichi Sankyo, including Daiichi Sankyo's investment in the resources necessary to successfully commercialize MINNEBRO in the territories where it is approved and to execute its commercial strategy; 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 discussed under the caption "Risk Factors" in Exelixis' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 1, 2018, 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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