Exelixis Licenses PI3K-Delta Program to Merck

December 21, 2011

Exelixis to receive $12M upfront payment and be eligible for potential development, regulatory and commercial milestones, plus royalties

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Dec. 21, 2011-- Exelixis, Inc. (NASDAQ:EXEL) today announced that it has granted to Merck, known as MSD outside of the United States and Canada, an exclusive worldwide license to its PI3K-delta research and development program, including XL499, the company's most advanced preclinical PI3K-delta inhibitor and other related compounds. Under the agreement, Merck will have a worldwide exclusive license and have sole responsibility to research, develop, and commercialize compounds originating from the program.

Merck will make an upfront payment of $12 million to Exelixis and Exelixis will be eligible for potential development and regulatory milestone payments for multiple indications of up to $239 million. Exelixis will also be eligible for potential combined sales performance milestones and royalties on net-sales of products emerging from the agreement. Milestones and royalties are payable on compounds emerging from Exelixis' PI3K-delta program or from certain compounds that arise from Merck's internal discovery efforts targeting PI3K-delta during a certain period.

"PI3K-delta is an interesting target with potential utility in a number of therapeutic areas, including inflammation and oncology," said Michael M. Morrissey, Ph.D., president and chief executive officer of Exelixis. "Our PI3K-delta program builds on our prior interest in the PI3K family, which led to the advancement of pan-PI3K inhibitors into clinical development for cancer. Merck's global presence and significant resources make it the ideal organization to carry the PI3K-delta program forward. At the same time, this agreement provides Exelixis with resources for the continued development and potential commercialization of our lead compound, cabozantinib, which is in late-stage development for medullary thyroid and prostate cancers."

"Exelixis has established a strong reputation for innovation in the development of targeted kinase inhibitors," said Don Nicholson, Ph.D., Vice President and Head of Worldwide Discovery, Respiratory and Immunology Franchise, Merck Research Laboratories. "Collaborations like this are an important part of our strategy as we seek new ways to address unmet needs in inflammatory disease and oncology."

PI3K-delta is a member of the Class 1 family of phosphoinositide-3 kinases and is predominantly expressed in cells of the immune system. Activation of PI3K-delta occurs in response to a variety of immune cell stimuli, and inappropriate PI3K-delta activation is thought to contribute to multiple inflammatory and allergic disorders, including rheumatoid arthritis and allergic asthma. Selectively targeting PI3K-delta has also shown potential in the treatment of certain lymphomas.

About Exelixis

Exelixis, Inc. is a biotechnology company committed to developing small molecule therapeutics for the treatment of cancer. Exelixis is focusing its proprietary resources and development efforts exclusively on cabozantinib, its most advanced solely-owned product candidate, in order to maximize the therapeutic and commercial potential of this compound. Exelixis believes cabozantinib has the potential to be a high-quality, differentiated pharmaceutical product that can make a meaningful difference in the lives of patients. Exelixis has also established a portfolio of other novel compounds that it believes have the potential to address serious unmet medical needs. For more information, please visit the company's web site at www.exelixis.com.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the payment to Exelixis of an upfront payment; Exelixis' potential receipt of development, regulatory and sales milestones, as well as royalties on sales of products; the clinical, therapeutic and commercial potential of the PI3K-delta program; the belief that Merck is the ideal organization to carry the PI3K-delta program forward; the belief that the agreement will provide resources for the continued development and potential commercialization of cabozantinib; and the clinical, therapeutic and commercial potential of cabozantinib. Words such as "will," "eligible," "potential," "emerging," "arise," "provides," "continued," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Exelixis' current plans, assumptions, beliefs and expectations. Forward-looking statements involve risks and uncertainties. Exelixis' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: risks related to Exelixis' dependence on the activities of Merck under the described agreement, the potential failure of the PI3K-delta program or cabozantinib to demonstrate safety and efficacy in clinical testing; the therapeutic and commercial value of the PI3K-delta program and cabozantinib; Exelixis' ability to conduct clinical trials of cabozantinib sufficient to achieve a positive completion; the sufficiency of Exelixis' capital and other resources; uncertain timing and level of expenses associated with the development of cabozantinib; the uncertainty of the FDA approval process; market competition; and changes in economic and business conditions. These and other risk factors are discussed under "Risk Factors" and elsewhere in Exelixis' quarterly report on Form 10-Q for the quarter ended September 30, 2011 and Exelixis' other filings with the Securities and Exchange Commission. 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.

Source: Exelixis, Inc.

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