Exelixis to Receive Milestone Payment from Bristol-Myers Squibb for Submission of Clinical Trial Authorization for RORγt Inverse Agonist Program

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SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Oct. 4, 2017-- Exelixis, Inc. (NASDAQ:EXEL) today announced that it has earned a $10 million milestone payment from Bristol-Myers Squibb under the terms of the two companies' worldwide collaboration for compounds targeting retinoic acid-related orphan receptor (ROR), a family of nuclear hormone receptors implicated in inflammatory conditions. The milestone payment was triggered by Bristol-Myers Squibb's filing of a Clinical Trial Authorization in Europe for a first-in-human study of a RORγt inverse agonist.

"Exelixis is closely focused on oncology today, but our legacy of drug discovery across diverse therapeutic areas lives on through our collaborations with our partners, including the RORγt inverse agonist program now advanced by Bristol-Myers Squibb," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "We congratulate Bristol-Myers Squibb on its plans for a first-in-human study and look forward to future updates."

From October 2010 to July 2013, Exelixis and Bristol-Myers Squibb undertook collaborative research around RORγt, with Exelixis and Bristol-Myers Squibb responsible for the discovery, optimization, and characterization of RORγt inverse agonists that could subsequently be developed and commercialized by Bristol-Myers Squibb. Since the end of the collaborative research period, Bristol-Myers Squibb has been solely responsible for all further research, development, manufacture, and potential commercialization of compounds developed under the collaboration, as well as all related costs and expenses. Exelixis received an upfront payment at the start of the collaboration in 2010, as well as a $2.5 million development milestone related to preclinical progress in February 2017. Exelixis could potentially receive additional development and regulatory milestones of up to $240 million, commercialization milestones of up to $150 million, and royalties on net sales depending on the advancement of the product candidate and eventual product.

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 them to patients globally. With growing revenues from the three resulting commercialized products – CABOMETYX®, COMETRIQ®, and COTELLIC® – we are reinvesting in our business to maximize the potential of our pipeline, which we intend to supplement 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. 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: Bristol-Myers Squibb's plans for a first-in-human study of a RORγt inverse agonist and its RORγt inverse agonist program generally; the potential for Exelixis to receive additional development, regulatory, and commercialization milestones, and royalties on sales under collaboration with Bristol-Myers Squibb; Exelixis' focus on the discovery, development and commercialization of cancer therapies; growing revenues from CABOMETYX, COMETRIQ, and COTELLIC 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; and Exelixis' mission to deliver the next generation of Exelixis medicines and help patients recover stronger and live longer. Words such as "plans," "strives," "could," "future," "further," "intend," "potential," "mission," 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 related to the potential failure of any RORγt inverse agonist to demonstrate safety and efficacy in clinical testing; Exelixis' dependence on its relationship with Bristol-Myers Squibb with respect to RORγt inverse agonists, including the level of Bristol-Myers Squibb's investment in the resources necessary to successfully develop, manufacture and commercialize any RORγt inverse agonists in territories where they are ultimately approved; risks and uncertainties related to regulatory review and approval processes; market acceptance of CABOMETYX, COMETRIQ, and COTELLIC and the availability of coverage and reimbursement for these products; 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' quarterly report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on August 2, 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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