Exelixis and Sanofi-aventis Sign Global License Agreement for XL147 & XL765 and Launch Broad Collaboration for Discovery of PI3K Inhibitors

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Exelixis to Receive $140 Million Upfront Payment and Guaranteed Research Funding

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--May. 28, 2009-- Sanofi-aventis (PARIS:SAN) and (NYSE:SNY) and Exelixis, Inc. (Nasdaq:EXEL) today announced a global license agreement for XL147 and XL765 and a broad collaboration for the discovery of inhibitors of phosphoinositide-3 kinase (PI3K) for the treatment of cancer. Activation of the PI3K pathway is a frequent event in human tumors, promoting cell proliferation, survival and resistance to chemotherapy and radiotherapy. Under the license, sanofi-aventis will have a worldwide exclusive license to XL147 and XL765, which are currently in phase 1 and phase 1b/2 clinical trials, and will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities. Exelixis will participate in conducting ongoing and potential future clinical trials and manufacturing activities.

Under the discovery collaboration, Exelixis and sanofi-aventis will combine efforts in establishing several pre-clinical PI3K programs and jointly share responsibility for research and preclinical activities related to isoform-selective inhibitors of PI3K. Sanofi-aventis will have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration; however, Exelixis may be responsible for conducting certain clinical trials.

Sanofi-aventis will pay Exelixis aggregate upfront cash payments of $140 million under the license and collaboration. Exelixis will also receive guaranteed research funding of $21 million over a three year research term under the collaboration. For the license and the collaboration, Exelixis will be eligible to receive development, regulatory and commercial milestones of over $1 billion in the aggregate, as well as royalties on sales of any products commercialized under the license or collaboration.

“Sanofi-aventis has a track record of success in commercializing innovative cancer therapies and is deeply committed to advancing the care of cancer patients,” said George A. Scangos, Ph.D., president and chief executive officer of Exelixis. “We believe that their expertise and resources will enable us to move aggressively in advancing the development of XL147 and XL765 and other potential PI3K inhibitors. The data generated to date in the XL147 and XL765 clinical programs suggest that these compounds may have utility in treating diverse cancers. Sanofi-aventis and Exelixis are committed to realizing the full potential of these compounds and other PI3K inhibitors to provide cancer patients with new treatment options.”

The effectiveness of the license and collaboration is subject to antitrust clearance under the Hart-Scott-Rodino Antitrust Improvements Act and other customary regulatory approvals.

Oral Presentations

Clinical data from the phase 1 trials of XL147 and XL765 will be presented at the 2009 American Society of Clinical Oncology Annual Meeting, which will be held from May 29 to June 2, 2009 in Orlando, Florida:

- “Phase 1 dose-escalation study of XL147, a PI3K inhibitor administered orally to patients with solid tumors” will be presented on Monday, June 1, 2009, starting at 1:30 p.m. local time (Abstract #3500)
- “A Phase 1 dose-escalation study of the safety, pharmacokinetics (PK) and pharmacodynamics of XL765, a PI3K/TORC1 /TORC2 inhibitor administered orally to patients (pts) with advanced solid tumors” will be presented on Monday, June 1, 2009 starting at 2:00 p.m. local time (Abstract #3502)

XL147 and XL765 target PI3K, which plays an important role in cell proliferation and survival. XL765 also inhibits the mammalian target of rapamycin (mTOR), which can be activated via upregulation of PI3K, or via PI3K-independent mechanisms. mTOR is frequently activated in human tumors and plays a central role in tumor cell proliferation.

Conference Call and Webcast

Exelixis will hold a live webcast today, Thursday, May 28, 2009, from 8:00 a.m. ET / 5:00 a.m. PT to 9:00 a.m. ET / 6:00 a.m. PT., during which Exelixis management will discuss the license and collaboration. The webcast may be accessed in the Event Calendar page under Investors at http://www.exelixis.com.

About Exelixis

Exelixis, Inc. is a development-stage biotechnology company dedicated to the discovery and development of novel small molecule therapeutics for the treatment of cancer and other serious diseases. The company is leveraging its fully integrated drug discovery platform to fuel the growth of its development pipeline, which is primarily focused on cancer. Currently, Exelixis’ broad product pipeline includes investigational compounds in phase 3, phase 2, and phase 1 clinical development. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including Bristol-Myers Squibb, GlaxoSmithKline, Genentech, Boehringer Ingelheim, Wyeth Pharmaceuticals, and Daiichi-Sankyo. For more information, please visit the company’s web site at www.exelixis.com.

Forward-Looking Statements

This press release contains forward-looking statements by Exelixis, including, without limitation, statements related to the anticipated effectiveness of the license and collaboration described in this press release; the companies’ plan for sanofi-aventis to have sole responsibility for all subsequent

clinical, regulatory, commercial and manufacturing activities with respect to XL147 and XL765 and for Exelixis to participate in conducting ongoing and potential future clinical trials and manufacturing activities; the companies' plan to combine efforts in establishing pre-clinical PI3K programs and jointly share responsibility for research and preclinical activities under the collaboration; the companies' plans for sanofi-aventis to have sole responsibility for all subsequent clinical, regulatory, commercial and manufacturing activities of any products arising from the collaboration and for Exelixis to potentially have responsibility for conducting certain clinical trials; Exelixis' receipt of upfront payments and guaranteed research funding; Exelixis' potential receipt of development, regulatory and commercial milestones, as well as royalties on sales of any products commercialized under the license or collaboration; and the future development path and commercial and therapeutic potential of XL147, XL765 and other potential PI3K inhibitors. Words such as "will," "may," "eligible," "believe," "suggest," "potential" 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 the potential failure of XL147, XL765 and other potential PI3K inhibitors to demonstrate safety and efficacy in clinical testing; the therapeutic and commercial value of XL147, XL765 and other potential PI3K inhibitors; the uncertainty of the FDA approval process; market competition; and Exelixis' dependence on its relationship with its collaboration partners. These and other risk factors are discussed under "Risk Factors" in Exelixis' Quarterly Report for the quarter ended April 3, 2009 and Exelixis' other reports filed 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.

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