



Exelixis Notifies GlaxoSmithKline of Proof-of-Concept for XL184

July 28, 2008

Data Report Submitted; Selection Decision Due in 90 Days

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--July 28, 2008--Exelixis, Inc. (Nasdaq:EXEL) today announced that it has notified GlaxoSmithKline (GSK) that it has achieved proof-of-concept for XL184 under the collaboration agreement between GSK and Exelixis, and has submitted the corresponding data report to GSK. Under the agreement, GSK has 90 days to review the data and decide whether to exercise its option to select the compound for further development and commercialization. If GSK selects XL184, Exelixis would receive a \$55 million milestone creditable by GSK against outstanding amounts under the loan facility between the parties, and potentially would receive commercialization milestones, royalties on product sales, and certain co-promotion rights in North America. Exelixis anticipates a decision from GSK by late October 2008.

"Achieving proof-of-concept for XL184 is an important milestone for Exelixis. Based on the anti-tumor activity presented at ASCO, we believe that XL184 shows great potential as a new therapy for patients with medullary thyroid cancer (MTC), for which no standard of care is currently available. Based on the current data in MTC and other cancers, we believe that XL184 strongly merits further development, either as part of our collaboration with GSK or by us independently," said Michael M. Morrissey, PhD, President of Research and Development at Exelixis.

XL184 is a small molecule anticancer compound targeting the MET, RET, and VEGFR2 receptor tyrosine kinases. Recently, on the basis of encouraging phase 1 trial data, Exelixis initiated a phase 3 registration trial of XL184 for the potential treatment of medullary thyroid cancer. Exelixis and the U.S. Food and Drug Administration had previously reached agreement on this phase 3 registration trial via the Special Protocol Assessment process. Exelixis has also discussed the trial design with European regulatory agencies.

Additional clinical studies with XL184 are ongoing to complement the pivotal trial in patients with MTC as part of Exelixis' strategy to rapidly advance compounds into areas of high unmet medical need, while potentially expanding into broader commercial markets by demonstrating activity in major tumor types. A phase 1b/2 trial of XL184 as a single agent and in combination with erlotinib was recently initiated in patients with non-small cell lung cancer. In addition, a phase 2 study of XL184 in patients with glioblastoma multiforme is ongoing.

Background on Exelixis-GSK Collaboration

In October 2002, Exelixis and GSK established a broad alliance to discover, develop, and commercialize novel therapeutics in the areas of vascular biology, inflammatory disease, and oncology. Under the terms of the collaboration, Exelixis is required to deliver to GSK a number of small molecule compounds that meet agreed-upon proof-of-concept criteria, and GSK has the right to select up to two of the compounds for further development and commercialization. GSK previously selected XL880 and will be able to choose one additional compound from among XL184, XL281, XL228, XL820, and XL844. Exelixis and GSK will bring the six-year collaboration to a successful conclusion on October 27, 2008, as scheduled. Exelixis will have the right to develop and commercialize compounds not selected by GSK, either alone or in collaboration with partners, with payment to GSK of a small royalty on sales of such compounds not selected by GSK. As a result of the conclusion of the collaboration, Exelixis' exclusivity obligations will be limited to the compounds selected by GSK. Exelixis will have the right to perform additional discovery, development, and commercialization efforts against any collaboration target or compound that does not infringe upon the intellectual property associated with compounds selected by GSK for further development and commercialization.

About XL184

XL184 inhibits MET, RET, and VEGFR2, which are key drivers of tumor growth, metastasis, survival, and angiogenesis. In pharmacodynamic studies in mice, oral administration of XL184 resulted in balanced and durable inhibition of these targets. The compound has also shown activity against common mutant forms of RET and MET. XL184 has exhibited dose-dependent tumor growth inhibition and tumor regression in a variety of preclinical tumor models, including breast cancer, colon cancer, MTC, non-small cell lung cancer, and glioblastoma.

About Medullary Thyroid Cancer

The American Cancer Society estimates that MTC accounts for 5% of all thyroid cancers. MTC occurs in sporadic and inherited forms (approximately 80% and 20% of MTC, respectively). Patients with the inherited form of MTC invariably have an activating mutation in RET in their germline DNA. Activating mutations in RET are also present in the tumor DNA of up to 50% of sporadic MTC patients with no familial history of thyroid cancer. MTC may metastasize to lymph nodes or other organs before it is ever diagnosed. Additionally, MTC does not take up radioactive iodine, which is commonly used to treat other types of thyroid cancers and to diagnose metastases. As a result, MTC is more difficult to treat than other thyroid cancers. There are no approved therapies for MTC; however, common treatments for MTC include surgery to remove malignant tissue, radiation therapy, and chemotherapy, all of which are associated with potential side effects, some of which may be long-term.

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 GlaxoSmithKline, Bristol-Myers Squibb, Genentech, Wyeth Pharmaceuticals, and Daiichi-Sankyo. For more information, please visit the company's website at <http://www.exelixis.com>.

Forward-Looking Statements

This press release contains forward-looking statements, including, without limitation, statements related to: the timing of a potential compound selection and milestone payment by GSK and the future development and potential efficacy of XL184. Words such as "would," "anticipate," "believe" 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: the potential failure of XL184 to demonstrate safety and efficacy in clinical testing; the therapeutic and commercial value of XL184; and Exelixis' ability to enter into new collaborations, continue existing collaborations and receive milestones and royalties under Exelixis' collaborative agreements. These and other risk factors are discussed under Risk Factors and elsewhere in Exelixis' quarterly report on Form 10-Q for the quarter ended March 28, 2008, and 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.

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