Bristol-Myers Squibb and Exelixis Enter Global Collaboration on Two Novel Cancer Programs

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Programs include XL184, a Phase III inhibitor of MET, VEGFR2 and RET, and XL281, a Phase I Inhibitor of RAF Kinase

PRINCETON, N.J. & SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) and Exelixis, Inc. (Nasdaq: EXEL) today announced a global collaboration covering two novel molecules for cancer with their associated development programs: Exelixis’ XL184, a small molecule inhibitor of MET, VEGFR2 and RET, which is currently in Phase III development for medullary thyroid cancer; and Exelixis’ XL281, a small molecule inhibitor of RAF kinase, which is currently in Phase I development for the treatment of patients with advanced solid tumor malignancies.

Under the terms of the collaboration, Bristol-Myers Squibb agreed to pay Exelixis an upfront cash payment of $195 million for the development and commercialization rights to both programs and to make additional license payments of $45 million in 2009.

The companies have agreed to co-develop XL184. Exelixis will have the option to co-promote XL184 in the United States. The companies will share worldwide development costs and commercial profits on XL184 in the United States. Exelixis will be eligible to receive sales performance milestones of up to $150 million and double-digit royalties on sales outside the United States. The clinical development of XL184 will be directed by a joint committee. It is anticipated that Exelixis will conduct a significant portion of clinical development activities through 2010. Exelixis may opt out of the co-development of XL184, in which case Exelixis would instead be eligible to receive development and regulatory milestones of up to $295 million, double-digit royalties on XL184 product sales worldwide, and sales performance milestones.

Bristol-Myers Squibb will receive an exclusive worldwide license to develop and commercialize XL281 and will be responsible for funding all future development. Exelixis is eligible for development and regulatory milestones of up to $315 million, sales performance milestones of up to $150 million and double-digit royalties on worldwide sales of XL281.

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For nearly a decade, the foundation for our close collaborations with Exelixis has been a commitment to discover and develop new medicines to help patients prevail over serious disease,” said Elliott Sigal, M.D., Ph.D., executive vice president, chief scientific officer, and president, Research and Development of Bristol-Myers Squibb. “XL184 and XL281 represent significant new opportunities to inhibit the progression of many different tumor types. This agreement represents the next step in our on-going String of Pearls initiative, designed to accelerate our company’s strategy to transform into a BioPharma leader by blending external scientific innovation with our own internal research and development expertise. Together with Exelixis, we intend to fully explore how these compounds can potentially extend the treatment options of patients with cancer.”

“There have been many attempts to blend the best of big pharma with the best of biotech, and over the years Exelixis and Bristol-Myers Squibb have learned how to do just that. This new collaboration maximizes the capabilities and strengths of each partner and sets the stage for the aggressive development of XL184 and XL281. The collaboration provides the development programs with appropriate resources and positions both compounds to be developed to their full potential in indications with significant commercial potential,” said George Scangos, president and chief executive officer of Exelixis. “Exelixis and Bristol-Myers Squibb are working toward a shared vision of maximizing the potential of these compounds to benefit patients who suffer from numerous types of cancer.”

XL184 provides a novel approach to the treatment of a variety of solid tumors where signaling through MET, VEGFR2 or RET plays an important role in dysregulated tumor growth and progression. XL184 has recently begun a Phase III clinical trial in medullary thyroid cancer, a disease in which RET mutations are found in a large proportion of patients. In addition, clinical trials to exploit the MET and VEGFR2 targeting of XL184 are ongoing in patients with non-small cell lung cancer and glioblastoma. Preclinically, XL184 also exhibits inhibitory activity for MET and VEGFR2 in a variety of breast, colon and brain tumor models.

XL281 is a novel small molecule designed to selectively inhibit RAF kinase, which lies immediately downstream of RAS and is a key component of the RAS/RAF/MEK/ERK kinase signaling pathway. The RAS/RAF/MEK/ERK pathway plays a key role in the transmission of growth-promoting signals downstream of receptor tyrosine kinases. Dysregulation of this pathway plays a pivotal role in the progression of many human tumors, and inhibition of the pathway may be useful in treating cancer. Phase II trials with this molecule are underway in order to select a dose and schedule for Phase II disease-directed trials.

The effectiveness of the agreement is subject to antitrust clearance under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.
About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to extend and enhance human life. For more information visit www.bms.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 III, Phase II and Phase I clinical development. Exelixis has established strategic corporate alliances with major pharmaceutical and biotechnology companies, including Bristol-Myers Squibb, GlaxoSmithKline, Genentech, Wyeth Pharmaceuticals and Daiichi-Sankyo. For more information, please visit the company's website at http://www.exelixis.com.

Exelixis Forward-Looking Statements

This press release contains forward-looking statements by Exelixis, including, without limitation, statements related to the potential effectiveness of the agreement described in this press release and Exelixis’ receipt of an upfront cash payment from Bristol-Myers Squibb; potential license and milestone payments by Bristol-Myers Squibb to Exelixis; the companies’ plan to share development costs and commercial profits and losses for XL184 in the United States; Exelixis’ potential receipt of royalties for XL184 products sales; Exelixis’ right to opt out of the co-development and co-promotion of XL184 in the United States and the related impact on potential royalties and milestones; Exelixis’ potential receipt of development, regulatory and sales milestones and royalties on worldwide sales of XL281; and the future funding, development path and commercial and therapeutic potential of XL184 and XL281 and associated compounds. Words such as “will,” “plan,” “eligible,” “may,” “shall,” “intend,” “potential,” “positions” 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 XL184 and XL281 to demonstrate safety and efficacy in clinical testing; the therapeutic and commercial value of XL184 and XL281; the uncertainty of the FDA approval process; market competition; and Exelixis’ dependence on its relationship with Bristol-Myers Squibb and ability to maintain its co-development rights under the collaboration. 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 26, 2008 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.

Bristol-Myers Squibb Forward-Looking Statements

This press release contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995, regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that the clinical trials described in this release will support a regulatory filing or that the products described in this release will receive regulatory approval. There can be no assurance that if approved, the products will be commercially successful. Forward-looking statements in the press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb’s business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2007, its Quarterly Reports on Form 10-Q, and Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise.

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