Bristol-Myers Squibb and Ono Enter into Strategic Agreement for Anti-PD-1 Antibody, BMS-936558/ONO-4538, and ORENCIA® (abatacept)

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PRINCETON, N.J. & OSAKA, Japan--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) and Ono Pharmaceutical Co., Ltd., today announced an agreement to expand Bristol-Myers Squibb’s territorial rights to develop and commercialize the anti-PD-1 antibody known as BMS-936558/ONO-4538, and to create a strategic alliance for the co-development and co-commercialization of ORENCIA® (abatacept) in Japan.

BMS-936558/ONO-4538, a fully human anti-PD-1 antibody, is an investigational cancer immunotherapy generated under a research collaboration entered into in May 2005 between Ono and Medarex, Inc. When Bristol-Myers Squibb acquired Medarex in 2009, it also acquired Medarex’s rights to develop and commercialize the anti-PD-1 antibody in North America. Under the terms of the agreement announced today, Ono will grant Bristol-Myers Squibb exclusive rights to develop and commercialize BMS-936558/ONO-4538 in the rest of the world, except in Japan, Korea and Taiwan where Ono has retained all rights to develop and commercialize BMS-936558/ONO-4538.

Also under the agreement, the companies will co-develop and co-commercialize ORENCIA, a biologic therapy for rheumatoid arthritis, in Japan. The agreement applies to both the currently approved intravenous (IV) formulation of ORENCIA and the subcutaneous (SC) formulation of ORENCIA, and includes all current and future indications. ORENCIA IV was launched in Japan in September 2010 by Bristol-Myers Squibb’s Japanese subsidiary, Bristol-Myers K.K., and is indicated for use in patients for whom other therapies have failed. ORENCIA SC is currently in Phase III development in Japan. Bristol-Myers K.K. will distribute and book sales of ORENCIA IV. Ono will distribute and book the sales of ORENCIA SC. The companies will jointly promote both formulations with Ono’s participation beginning when the post-marketing surveillance period for ORENCIA IV has concluded, which is expected to be in 2013.

“Our granting of exclusive rights to Bristol-Myers Squibb for this exciting new agent in Japan is due to the strategic value of this compound, and the strong spin-off potential it provides,” said Fumio Takeda, president of Electronic Business Strategy, Ono. "We will also continue to develop and commercialize ORENCIA SC in Japan, and we look forward to a successful launch of BMS-936558/ONO-4538 in the US and elsewhere as the result of this strategic collaboration.”

“Bristol-Myers Squibb is pleased to enter into this important collaboration with Ono Pharmaceutical that further enhances our position as a leader in immuno-oncology,” said Lamberto Andreotti, chief executive officer, Bristol-Myers Squibb. “Obtaining expanded rights to this anti-PD-1 antibody through our String of Pearls strategy will enable broader global development of this promising cancer immunotherapy as we continue to build our pipeline and understanding in this exciting area.”

“In addition we are very pleased to be able to continue the important work of bringing ORENCIA to patients in Japan with Ono, a highly-respected Japanese company. We believe that our collective resources will benefit the rheumatoid arthritis patients we serve.”

“We are delighted to further strengthen the relationship already established between Ono and Bristol-Myers Squibb. BMS-936558/ONO-4538 represents a promising investigational agent in the emerging field of immuno-oncology. Together with Bristol-Myers Squibb we will be better able to quickly bring this potential new medicine to patients in need worldwide,” said Gyo Sagara, president, representative director and CEO of Ono Pharmaceutical.

“ORENCIA has an innovative mechanism of action to suppress the inflammation pathway in rheumatoid arthritis. We are also very delighted to collaborate with Bristol-Myers Squibb on such an important product. Adding ORENCIA will expand our product portfolio in orthopedics, one of our strategic therapeutic areas.”

About BMS-936558/ONO-4538

BMS-936558/ONO-4538 is a fully human antibody directed against PD-1 (Programmed cell death 1). PD-1 is expressed on the surface of activated T cells and is involved in the negative regulation of the immune response to tumor cells. Tumor cells are reported to suppress the host’s immune response and escape from its immunological attack through activation of PD-1. BMS-936558/ONO-4538 is expected to normalize the host’s immune response by blocking the binding of tumor cells to PD-1 thus potentially allowing the immune system to work against the tumor cells. In the U.S., BMS-936558/ONO-4538 is in Phase I and Phase II development across a variety of tumor types and treatment settings, including renal cell carcinoma and melanoma. In Japan, a Phase II clinical study for melanoma is under preparation by Ono.

About ORENCIA in Japan

Rheumatoid arthritis is an autoimmune disease characterized by inflammation of the joints as a result of the over-expression of pro-inflammatory cytokines. ORENCIA is a biologic therapy that works by inhibiting T-cell activation and suppressing the production of pro-inflammatory cytokines, which leads to the amelioration of the inflammation in joints of patients.

ORENCIA IV is available in more than 50 counties, and was launched in September 2010 in Japan where it is indicated for use in patients of rheumatoid arthritis for whom other therapies have failed.
About Bristol-Myers Squibb

Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information about Bristol-Myers Squibb, visit www.bms.com, or follow us on Twitter at http://twitter.com/bmsnews.

ORENCIA is a registered trademark of Bristol-Myers Squibb.

About Ono Pharmaceutical

Ono Pharmaceutical Co., Ltd. is a R&D-oriented pharmaceutical company specializing in creating innovative medicines in specific areas and is headquartered in Osaka, Japan. For more information about Ono, visit the company’s website at www.ono.co.jp.

Bristol-Myers Squibb Forward Looking Statement

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 investigational compound described in this release will move from early stage development into full product development, that clinical trials of this compound will support a regulatory filing, or that this compound will receive regulatory approval or, if approved, become a commercially successful product. 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, 2010, 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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