



ONO PHARMACEUTICAL CO., LTD. and Bristol-Myers Squibb Announce Strategic Immuno-Oncology Collaboration in Japan, South Korea and Taiwan

Companies to develop and commercialize Opdivo® (nivolumab), ipilimumab, and three early-stage clinical immuno-oncology assets as single agents and combination regimens

ONO strengthens its immuno-oncology portfolio with access to additional assets

Bristol-Myers Squibb gains access to Opdivo in Japan, South Korea and Taiwan, broadening company's leadership in immuno-oncology

Collaboration will leverage global clinical trials by including patients from Japan, South Korea and Taiwan

(NEW YORK and OSAKA – July 23, 2014) - ONO PHARMACEUTICAL CO., LTD. ("ONO") and Bristol-Myers Squibb Company (NYSE: BMY) have signed a strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies as single agents and combination regimens to help address the unmet medical needs of patients with cancer in Japan, South Korea and Taiwan. As part of the agreement, ONO and Bristol-Myers Squibb will jointly develop and commercialize *Opdivo*® (nivolumab) and ipilimumab (brand name outside Japan: *Yervoy*®) across a broad range of tumor types.

Opdivo® is a PD-1 immune checkpoint inhibitor approved in Japan for the treatment of patients with unresectable melanoma, making it the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world, and is being developed in multiple tumor types in more than 35 clinical trials. Ipilimumab, a CTLA-4 immune checkpoint inhibitor, is approved in Taiwan for the treatment of patients with advanced melanoma who have received prior therapy, and is in late stage development as a potential treatment option for melanoma, small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC) in Japan. The agreement includes three additional early-stage clinical immuno-oncology assets from Bristol-Myers Squibb: lirilumab, an antibody that blocks the KIR receptor on natural killer cells, urelumab, an agonist of the CD137 co-stimulatory receptor, and BMS-986016, a LAG3 immune checkpoint inhibitor.

ONO and Bristol-Myers Squibb will jointly pursue development of monotherapy and combination regimens, with *Opdivo*[®] as the foundational therapy in Japan, South Korea and Taiwan, and leverage global clinical trials by including patients from the three countries.

"Our collaboration with Bristol-Myers Squibb strengthens our ability to further enhance the potential of *Opdivo*®, for which ONO recently received manufacturing and marketing approval in Japan

as the first PD-1 inhibitor approved anywhere in the world," said Gyo Sagara, President, Representative Director and CEO, ONO. "By pursuing the study of investigational combination regimens of immunotherapies with Bristol-Myers Squibb, we hope to bring a range of new therapeutic options to cancer patients."

"Bristol-Myers Squibb's collaboration with ONO supports our goal to maximize the full potential of our immuno-oncology portfolio for patients worldwide," said Lamberto Andreotti, chief executive officer, Bristol-Myers Squibb. "This collaboration combines our leadership in immuno-oncology with both companies' experience and capabilities in Asia, and strengthens our long-standing relationship with ONO."

Under the terms of the agreement, ONO and Bristol-Myers Squibb will jointly develop and commercialize all collaboration products in Japan, South Korea and Taiwan. Development costs and commercial profits will be shared equally when $Opdivo^{@}$ is used in combination with any Bristol-Myers Squibb compound (Ipilimumab, lirilumab, urelumab, BMS-986016). When $Opdivo^{@}$ is used as a single agent, ONO will fund the substantial majority of development costs and receive the substantial majority of commercial profits. For a Bristol-Myers Squibb compound used as monotherapy, or two Bristol-Myers Squibb compounds used in a combination regimen, Bristol-Myers Squibb will fund the substantial majority of development costs and receive the substantial majority of commercial profits.

Prior to this announcement, ONO held exclusive rights to develop and commercialize *Opdivo*[®] in Japan, South Korea and Taiwan while Bristol-Myers Squibb held such rights in the rest of the world, along with sole rights to develop and commercialize ipilimumab, lirilumab, urelumab, and BMS-986016 worldwide.

About *Opdivo*[®] (nivolumab)

Cancer cells may exploit "regulatory" pathways, such as checkpoint pathways, to hide from the immune system and shield the tumor from immune attack. $Opdivo^{@}$ is an investigational human PD-1 immune checkpoint inhibitor that binds to the checkpoint receptor PD-1 (programmed death-1) expressed on activated T-cells. The companies are investigating whether by blocking this pathway, $Opdivo^{@}$ would enable the immune system to resume its ability to recognize attack and destroy cancer cells.

Opdivo® was approved in Japan on July 4, 2014 for the treatment of patients with unresectable melanoma and is studied in multiple tumor types consisting of more than 35 trials – as monotherapy or in combination with other therapies – in which more than 7,000 patients have been enrolled worldwide. Among these are several potentially registrational trials in NSCLC, melanoma, renal cell carcinoma (RCC), head and neck cancer, glioblastoma and non-Hodgkin lymphoma. In 2013, the FDA granted Fast Track designation for Opdivo® in NSCLC, melanoma and RCC. In May 2014, the FDA granted Opdivo®

Breakthrough Therapy Designation for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant and brentuximab.

About ipilimumab (brand name outside Japan: Yervoy®)

Ipilimumab, which is a recombinant, human monoclonal antibody, blocks the cytotoxic T-lymphocyte-associated antigen-4 (CTLA-4). CTLA-4 is a negative regulator of T-cell activation. Ipilimumab binds to CTLA-4 and blocks the interaction of CTLA-4 with its ligands, CD80/CD86. Blockade of CTLA-4 has been shown to augment T-cell activation and proliferation. The mechanism of action of ipilimumab's effect in patients with melanoma is indirect, possibly through T-cell mediated antitumor immune responses. On March 25, 2011, the FDA approved ipilimumab 3 mg/kg monotherapy for patients with unresectable or metastatic melanoma. Ipilimumab is now approved in more than 40 countries, including Taiwan. There is a broad, ongoing development program in place for ipilimumab spanning multiple tumor types. This includes Phase 3 trials in prostate and lung cancers.

Immuno-Oncology at Bristol-Myers Squibb

Surgery, radiation, cytotoxic or targeted therapies have represented the mainstay of cancer treatment over the last several decades, but long-term survival and a positive quality of life have remained elusive for many patients with advanced disease.

To address this unmet medical need, Bristol-Myers Squibb is leading advances in the innovative field of immuno-oncology, which involves agents whose primary mechanism is to work directly with the body's immune system to fight cancer. The company is exploring a variety of compounds and immunotherapeutic approaches for patients with different types of cancer, including researching the potential of combining immuno-oncology agents that target different and complementary pathways in the treatment of cancer.

Bristol-Myers Squibb is committed to advancing the science of immuno-oncology, with the goal of changing survival expectations and the way patients live with cancer.

About the ONO and Bristol-Myers Squibb Collaboration

ONO and Bristol-Myers Squibb, through its wholly owned subsidiary Medarex, Inc., have a long-standing relationship since 2005 to develop and commercialize PD-1 antibodies, including *Opdivo*[®]. Bristol-Myers Squibb obtained rights to develop and commercialize *Opdivo*[®] in North America in 2009 as part of the Medarex, Inc. acquisition. Through a collaboration agreement entered into in September 2011, ONO granted Bristol-Myers Squibb exclusive rights to develop and commercialize *Opdivo*[®] in the rest of the world, except in Japan, South Korea and Taiwan where ONO retained such rights.

On July 23, 2014, ONO and Bristol-Myers Squibb signed a new collaboration agreement in which the companies agreed to jointly develop and commercialize *Opdivo*[®], ipilimumab and three early-stage immunotherapies in Japan, South Korea and Taiwan.

About ONO PHARMACEUTICAL CO., LTD.

ONO PHARMACEUTICAL CO., LTD., headquartered in Osaka, Japan, is an R&D-oriented pharmaceutical company committed to creating innovative medicines in specific areas. It focuses especially on the diabetes and oncology areas. For more information, please visit the company's website at http://www.ono.co.jp/eng/index.html.

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, please visit www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.

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 any of the compounds mentioned in this release will receive regulatory approval in Japan, South Korea or Taiwan, either as single agents (other than Yervoy in Taiwan and Opdivo in Japan) or in combination regimens, or, if approved, that they will become commercially successful products. Forward-looking statements in this 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, 2013 in our Quarterly Reports on Form 10-Q and our 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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