Bristol-Myers Squibb Granted Exclusive License by Ono Pharmaceutical for Multiple Programs Targeting Immuno-Suppressive Factors in the Tumor Microenvironment

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- **Bristol-Myers Squibb to develop and commercialize ONO-4578, Ono’s Phase 1 selective Prostaglandin E \(_2\) (PGE \(_2\) ) receptor 4 (EP \(_4\) ) antagonist**
- **Strengthens Bristol-Myers Squibb’s oncology development program with potential to expand and enhance the benefit of immunotherapy in a broad range of tumor indications**
- **Expands companies’ Immuno-Oncology alliance established in 2014**

PRINCETON, N.J. & OSAKA, Japan--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) and Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; “Ono”) announced an agreement that grants Bristol-Myers Squibb an exclusive license for the development and commercialization of ONO-4578, Ono’s selective Prostaglandin E\(_2\) (PGE\(_2\)) receptor 4 (EP\(_4\)) antagonist. The companies will also collaborate on discovery efforts to identify additional compounds from Ono’s PGE\(_2\) receptor antagonist programs.

“To improve long-term outcomes for more patients with cancer, we believe more Immuno-Oncology based combinations may be required, and we are pleased to continue our long-standing collaboration with Ono with this focus in mind,” said Fouad Namouni, M.D., head of Development, Oncology, Bristol-Myers Squibb. “Ono’s Prostaglandin E\(_2\) receptor antagonist programs offer the potential to develop targeted therapies that counteract the effects of an immunosuppressive tumor microenvironment. Researching Prostaglandin E\(_2\) receptor antagonists in combination with our oncology portfolio has the potential to result in an enhanced response in a broad range of tumors.”

“We are very pleased to collaborate with Bristol-Myers Squibb on ONO-4578, an innovative Immuno-Oncology therapy candidate derived from our long-standing Prostaglandin projects, and to further work with Bristol-Myers Squibb on other Prostaglandin E\(_2\) receptor antagonist programs,” said Hiroshi Awata, Vice President Executive Officer and Executive Director, Clinical Development, Ono Pharmaceutical Co., Ltd. “We are committed to further pursuing the worldwide development of ONO-4578 with Bristol-Myers Squibb with the goal of improving outcomes of patients suffering from cancer around the world as promptly as possible.”

Under the terms of the agreement, Bristol-Myers Squibb will make an upfront payment of $40 million to Ono. Bristol-Myers Squibb will be solely responsible for the development, manufacturing and commercialization of ONO-4578 as well as other PGE\(_2\) receptor antagonist products in all countries of the world except Japan, South Korea, Taiwan, China and Association of Southeast Asian Nations (ASEAN) countries. Ono is eligible to receive subsequent clinical, regulatory and sales-based milestone payments, as well as royalties in these countries where Bristol-Myers Squibb has exclusive license. In Japan, South Korea and Taiwan, Bristol-Myers Squibb and Ono will partner on the development and commercialization under the companies’ existing collaboration agreement, while in China and ASEAN countries, Ono will retain exclusive rights.

**About Prostaglandin E\(_2\) and Immuno-Oncology**

Prostaglandin E\(_2\) (PGE\(_2\)), a major immunosuppressive factor in the tumor microenvironment, is believed to suppress tumor immunity and promote tumor progression. Preclinical data suggests that modulation of PGE\(_2\) through any PGE\(_2\) receptor antagonists may complement Immuno-Oncology therapies, including anti-PD-1 and anti-CTLA-4, and potentially increase both the rate and durability of response in tumors that are refractory to immunotherapy. Certain patients and tumor types have higher expression of PGE\(_2\)-related molecules and/or immune characteristics that are more likely to respond to PGE\(_2\) receptor blockade, presenting an opportunity for patient stratification to improve outcomes.
About ONO-4578

ONO-4578 is a selective, oral antagonist of EP₄, which is a Prostaglandin E₂ receptor. In results from experiments using mouse models, ONO-4578 showed an anti-tumor effect by improving immunosuppressive tumor microenvironment. Ono has already commenced Phase I clinical study of ONO-4578 in Japan.

About the Bristol-Myers Squibb and Ono Pharmaceutical Collaboration

In 2011, through a collaboration agreement with Ono Pharmaceutical Co., Ltd., Bristol-Myers Squibb expanded its territorial rights to develop and commercialize Opdivo globally except in Japan, South Korea and Taiwan, where Ono had retained all rights to the compound at the time. On July 23, 2014, Ono and Bristol-Myers Squibb further expanded the companies’ strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agents and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

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 us at BMS.com or follow us on LinkedIn, Twitter, YouTube and Facebook.

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, especially in oncology and diabetes areas. For more information, please visit the company’s website at http://www.ono.co.jp/eng/index.html.

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 ONO-4578 or any other compounds from the PGE₂ receptor programs will be successfully developed or approved for any of the indications described in this release. 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, 2016, 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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