

June 4th, 2012

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Fully Human Anti-PD-1 Antibody “ONO-4538/BMS-936558”

Results from Phase 1 Study in Cancer Patients Published in New England Journal of Medicine (NEJM) and Presented at Annual Meeting of the American Society of Clinical Oncology (ASCO)

Bristol-Myers Squibb Company (hereinafter referred to as “BMS”) announced the results from Phase 1 study in patients with non-small-cell lung cancer (NSCLC), metastatic melanoma and renal cell carcinoma (RCC) to be published in New England Journal of Medicine (NEJM) and presented at 48th Annual Meeting of the American Society of Clinical Oncology (ASCO), on June 2nd (US time).

ONO-4538/BMS-936558, a fully human anti-PD-1 antibody, is an investigational cancer immunotherapy generated under a research collaboration entered into in May 2005 between Ono Pharmaceutical Co., Ltd. (hereinafter referred to as “Ono”) and Medarex, Inc. When Medarex, Inc. was acquired by BMS in 2009, it also granted BMS its rights to develop and commercialize the anti-PD-1 antibody in North America. Through the collaboration agreement entered into in September 2011 between Ono and BMS, Ono granted BMS exclusive rights to develop and commercialize ONO-4538/BMS-936558 in the rest of the world, except in Japan, Korea and Taiwan where Ono has retained all rights to develop and commercialize the compound.

BMS is conducting a Phase 2 study in RCC in North America and Europe, and plans to initiate registrational studies for anti-PD-1 this year in NSCLC and RCC, and late 2012, early 2013 for metastatic melanoma. On the other hand, Ono is conducting a Phase 2 study in metastatic melanoma in Japan, and plans to initiate clinical studies in RCC and NSCLC, taking account of the development status in United States and Europe.

Attached from the following page is the press release made by BMS for your information.



Investigational Anti-PD-1 Immunotherapy BMS-936558 Showed Clinical Activity in Phase 1 Trial of Patients with Previously-Treated Non-Small-Cell Lung Cancer, Metastatic Melanoma and Renal Cell Cancer

- *Clinical Activity of Anti-PD-1 Published in New England Journal of Medicine (NEJM) and Presented at 48th Annual Meeting of the American Society of Clinical Oncology (ASCO)*
- *Anti-PD-1 Registrational Development Programs for NSCLC and RCC to Start this Year; Metastatic Melanoma to Start Late 2012, Early 2013*
- *Data Broaden Scientific Understanding of the Field of Immuno-Oncology*

(PRINCETON, New Jersey - June 2, 2012) – [Bristol-Myers Squibb Company](#) (NYSE: BMY)

today announced interim results from the expanded Phase 1 dose-ranging study 003 (n=296) of its investigational anti-PD-1 immunotherapy (BMS-936558), which showed clinical activity in patients with previously-treated non small-cell lung cancer (NSCLC), metastatic melanoma and renal cell carcinoma (RCC). Anti-PD-1 is a fully-human antibody that targets the inhibitory receptor expressed on activated T-cells called PD-1 or programmed death-1. Objective response rates (ORs) across dose cohorts, as measured by standard RECIST criteria, ranged from 6% to 32% in NSCLC, 19% to 41% in metastatic melanoma and 24% to 31% in RCC. Most responses were durable.

Drug-related serious adverse events occurred in 11% of patients who received BMS-936558. Drug-related adverse events of special interest, defined as those with potential immune-related etiology, were sometimes severe and life-threatening.

The data on anti-PD-1 were published today in the *New England Journal of Medicine*¹ and featured in four oral presentations at the 48th Annual Meeting of the American Society of Clinical Oncology (Abstract # 2509, 4505, 7509 and 8507). Additionally, abstracts from the NSCLC cohort

¹ Topalian et al the Johns Hopkins University School of Medicine and the Sidney Kimmel Comprehensive Cancer Center.

(Abstract# 7509) and the melanoma cohort (Abstract #8507) of study 003 have been chosen for the Best of ASCO® educational program.

“Results from this Phase 1 study of anti-PD-1 showed clinical activity across NSCLC, metastatic melanoma and RCC, adding to our scientific understanding of the potential of immuno-oncology as a therapeutic approach in the treatment of cancer,” said Dr. Thomas J. Lynch, Jr., director of Yale Cancer Center and physician-in-chief of the Smilow Cancer Hospital at Yale-New Haven, which was involved in the clinical trials. “These data are encouraging and support further investigation of anti-PD-1 in large-scale, randomized Phase 3 trials.”

“Immuno-oncology is a prioritized area of research and development at Bristol-Myers Squibb and we plan to initiate registrational studies for anti-PD-1 in NSCLC and RCC this year and late 2012, early 2013 for metastatic melanoma,” said [Brian Daniels](#), senior vice president, Global Development and Medical Affairs, Bristol-Myers Squibb. “Our commitment to advancing the science of immuno-oncology is underscored by the data presented at ASCO and published in the *New England Journal of Medicine*, our ongoing development programs for immuno-oncology assets including [YERVOY®](#) (ipilimumab) and anti-PD-1, and the investment in the International Immuno-Oncology Network, a collaboration with leading cancer research centers.”

Through a collaboration agreement with Ono Pharmaceutical, Bristol-Myers Squibb expanded its territorial rights to develop and commercialize anti-PD-1 (BMS-936558/ONO-4538) globally except in Japan, Korea and Taiwan where Ono has retained all rights to the compound.

Study 003 Interim Results

Objective responses, as measured by standard RECIST criteria, were observed in patients treated with BMS-936558 across dose cohorts and across the NSCLC (6% to 32%), metastatic melanoma (19% to 41%) and RCC (6% to 32%) tumor types. Most responses were durable with response durations ≥ 1 year in 65% of responders with ≥ 1 year follow-up.

The spectrum, frequency, and severity of treatment-related adverse events (AEs) were generally similar across tested dose levels. Common drug-related AEs included fatigue, rash, diarrhea, decreased appetite and nausea, with Grade 3-4 AEs observed in 14% of patients. Drug-related AEs of special interest, defined as those with potential immune-related etiologies, included pneumonitis, vitiligo, colitis, hepatitis, hypophysitis and thyroiditis. Hepatic or gastrointestinal AEs were managed with treatment interruption and administration of corticosteroids, as needed. Endocrine disorders were managed with replacement therapy. Drug-related pneumonitis occurred in 9 of 296 (3%) patients. Grade 3-4 pneumonitis developed in 3 (1%) patients and was associated with 3 drug-related deaths.

About Study 003

Study 003 is a dose-ranging Phase 1 study (n=296) evaluating the safety, antitumor activity and pharmacokinetics of BMS-936558 in patients with advanced melanoma (n=104), non-small cell lung cancer (n=122), renal cell carcinoma (n=34), castration-resistant prostate cancer (n=17) and colorectal cancer (n=19).

Eligible patients were administered BMS-936558 as an intravenous infusion every 2 weeks of each 8-week treatment cycle. Cohorts of three to six patients per dose level (0.1, 0.3, 1.0, 3.0 or 10 mg/kg) were enrolled sequentially. Patients continued treatment ≤ 2 years (12 cycles), unless they experienced complete response, unacceptable toxicity, progressive disease or withdrew consent. In clinically stable patients, treatment could be continued beyond apparent initial disease progression until confirmed progression, as defined by proposed immune response criteria. Patients with stable disease (SD) or an ongoing OR at the completion of treatment were followed for ≤ 1 year and offered retreatment for one additional year if their disease progressed. OR was defined as complete (CR) or partial response (PR).

Immuno-Oncology at Bristol-Myers Squibb

Immuno-oncology, which focuses on the scientific potential of harnessing the unique properties of the immune system to fight cancer, is a prioritized area of research and development at Bristol-Myers Squibb. The Company is committed to leading advances in this important field of research and is exploring a variety of innovative compounds and immunotherapeutic approaches to help address significant unmet medical needs in a broad range of cancers. More information can be found at www.BMSImmunoOncology.com.

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>.

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 all of the compounds described in this release will move from exploratory development into full product development, that the clinical trials of these compounds will support regulatory filings, or that all of the compounds will receive regulatory approvals or, if approved, that they will all 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, 2011, 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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