October 31, 2014

Phase 2 Objective Response Rates and Survival Data for *Opdivo* (nivolumab) in Heavily Pre-treated Advanced Squamous Cell Non-Small Cell Lung Cancer to be Presented at the 2014 Chicago Multidisciplinary Symposium on Thoracic Oncology

(PRINCETON, NJ, October 30, 2014) – Bristol-Myers Squibb Company (NYSE: BMY) announced results from CheckMate -063, a Phase 2 single-arm, open-label study of *Opdivo* (nivolumab), an investigational PD-1 immune checkpoint inhibitor, administered as a single agent in patients with advanced squamous cell non-small cell lung cancer (NSCLC) who have progressed after at least two prior systemic treatments with 65% receiving three or more prior therapies (n=117).

Opdivo is a human anti-human PD-1 monoclonal antibody generated under a research collaboration entered into in May 2005 between ONO PHARMACEUTICAL CO.,LTD. (“ONO”) and the US-based company Medarex,Inc. When Medarex, Inc. was acquired by BMS in 2009, it also granted BMS its rights to develop and commercialize the human anti-human PD-1 monoclonal 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 Opdivo in the rest of the world, except in Japan, Korea and Taiwan where ONO had retained all rights to develop and commercialize the compound. On July 23, 2014, ONO and BMS 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.
Late in September, FDA accepted for priority review the Biologics License Application for previously treated advanced melanoma based on data from first Phase 3 randomized trial of Opdivo. Agency granted second breakthrough therapy designation for Opdivo. European Medicines Agency validated the Marketing Authorization Application for advanced melanoma. Accelerated assessment has also been granted for this application. Also EMA validated for review the Marketing Authorization Application (MAA) for Opdivo in non-small cell lung cancer (NSCLC).

Furthermore, BMS has a robust clinical development program in a variety of tumor types overseas, including: Non-Small Cell Lung Cancer (NSCLC), Renal Cell Carcinoma (RCC), Melanoma, Head and Neck Cancer, Blood Cancer, Glioblastoma, Colorectal Cancer, Pancreatic Cancer, Gastric Cancer, Hepatocellular Carcinoma, Triple-Negative Breast Cancer, Small-Cell Cancer, Bladder Cancer. In Japan, ONO has launched it for melanoma treatment in September 2014. Also, ONO is conducting clinical development programs including RCC, NSCLC, Head and Neck Cancer, Gastric Cancer and esophageal cancer.

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

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Phase 2 Objective Response Rates and Survival Data for *Opdivo* (nivolumab) in Heavily Pre-treated Advanced Squamous Cell Non-Small Cell Lung Cancer to be Presented at the 2014 Chicago Multidisciplinary Symposium on Thoracic Oncology

- *In CheckMate -063, the objective response rate was 15% in patients treated with single agent Opdivo and the median duration of response was not reached*
- *41% of Opdivo-treated patients were alive at one year*
- *Types and frequency of treatment-related adverse events were consistent with early clinical experience and managed using recommended treatment algorithms*
- *Rolling submission initiated with FDA in April based on CheckMate -063; company expects to complete submission by year end*

(PRINCETON, NJ, October 30, 2014) – Bristol-Myers Squibb Company (NYSE: BMY) today announced results from CheckMate -063, a Phase 2 single-arm, open-label study of *Opdivo* (nivolumab), an investigational PD-1 immune checkpoint inhibitor, administered as a single agent in patients with advanced squamous cell non-small cell lung cancer (NSCLC) who have progressed after at least two prior systemic treatments with 65% receiving three or more prior therapies (n=117). With approximately 11 months of minimum follow up, the objective response rate (ORR, the study's primary endpoint) was 15% (95% CI = 8.7, 22.2) as assessed by an independent review committee (IRC) using RECIST 1.1 criteria and the median duration of response was not reached. The estimated one-year survival rate was 41% (95% CI = 31.6, 49.7) and median overall survival (mOS) was 8.2 months (95% CI = 6.05, 10.91). These data will be presented during the Plenary Session at the 2014 Chicago Multidisciplinary Symposium on Thoracic Oncology on October 31 (Abstract #3462).

"The Phase 2 findings from CheckMate -063 are encouraging as there are no effective treatment options for patients with refractory squamous cell lung cancer after their disease has progressed through two prior therapies," said Suresh S. Ramalingam, MD, Professor and Director of Medical Oncology, Winship Cancer Institute of Emory University. "The results are also consistent with Phase 1 data previously reported from Study -003." Historically, the expected one-year survival rate for third-line squamous cell NSCLC patients is approximately 5.5% - 18%.[i,ii]

Grade 3-4 drug-related adverse events (AEs) were reported in 17.1% of patients. The most common Grade 3-4 AEs (greater than or equal to 2%) were fatigue (4.3%), pneumonitis (3.4%), and diarrhea (2.6%). Discontinuations due to drug-related AEs of any grade occurred in 12% of patients and

there were two drug-related deaths in patients with multiple comorbidities and in the setting of progressive disease.

"Results from CheckMate -063 offer further clinical evidence of the potential of immuno-oncology as an innovative approach to treating this disease," said Michael Giordano, senior vice president, Head of Development, Oncology. "We are committed to addressing the significant unmet medical needs of patients with lung cancer and have the broadest development program evaluating our approved and investigational immuno-oncology agents across multiple lines of therapy and histology."

Bristol-Myers Squibb's lung cancer research and development program is evaluating its approved and investigational immunotherapies – either as single agents or as part of combination regimens – across lines of therapy, histologies and biomarker expression. Among these are six ongoing Phase 3 trials. Four Phase 3 trials are evaluating *Opdivo* as a single agent in patients – three in previously treated patients (CheckMate -017, CheckMate -057 and CheckMate -153) and one in chemotherapy-naïve patients (CheckMate -026). Two Phase 3 trials evaluating Yervoy in combination with chemotherapy in newly diagnosed small cell lung cancer (Study -156) and squamous cell NSCLC (Study -104) are ongoing.

Bristol-Myers Squibb has proposed the name *Opdivo* (pronounced op-dee-voh), which, if approved by health authorities, will serve as the trademark for nivolumab.

About the Checkmate 063 Trial Design & Detailed Results

Checkmate -063 is a Phase 2 single arm, open-label study designed to assess advanced squamous cell NSCLC patients who progressed after both platinum-based therapy and at least one additional systemic therapy with an ECOG Performance Status of 0 or 1 who were treated with *Opdivo* as a single agent 3mg/kg by intravenous infusion every two weeks until disease progression or treatment discontinuation (n=117). The primary endpoint was ORR as assessed by an IRC using RECIST 1.1 criteria. Responders were further characterized by duration of response. Secondary endpoints included investigator-assessed ORR. Overall survival, PFS and efficacy by PD-L1 expression status were exploratory endpoints. All treated patients had received at least two prior systemic regimens with 65% receiving greater than or equal to three prior therapies. Seventy-six percent of patients were within three months of completion of their most recent therapy. The best response to the most recent prior systemic therapy was progressive disease in 61% of patients.

With approximately 11 months of minimum follow up, the ORR was 15% (95% CI = 8.7, 22.2) as assessed by an IRC using RECIST 1.1 criteria and the median duration of response was not reached. The estimated one-year survival rate was 41% (95% CI = 31.6, 49.7) and mOS was 8.2 months (95% CI

= 6.05, 10.91). An additional 26% of patients had stable disease with a median duration of six months (95% CI, 4.73, 10.91) giving a disease control rate (defined as partial response + stable disease) of 41%. For patients with quantifiable PD-L1 expression, responses were observed independent of PD-L1 status.

Grade 3-4 drug-related AEs were reported in 17.1% of patients. The most common (greater than or equal to 2%) Grade 3-4 AEs were fatigue (4.3%), pneumonitis (3.4%), and diarrhea (2.6%). Drug-related AEs generally were manageable with corticosteroids and/or supportive care as per established safety algorithms. Discontinuations due to drug-related AEs of any grade occurred in 12% of patients and there were two drug-related deaths in patients with muliple comorbidities and in the setting of progressive disease.

About *Opdivo*

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, fully-human PD-1 immune checkpoint inhibitor that binds to the checkpoint receptor PD-1 (programmed death-1) expressed on activated T-cells.

Bristol-Myers Squibb has a broad, global development program to study *Opdivo* 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* (nivolumab) in NSCLC, melanoma and RCC. In April 2014, the company initiated a rolling submission with the FDA for *Opdivo* in third-line pre-treated squamous cell NSCLC based on CheckMate -063 and expects to complete the submission by year-end. The FDA granted *Opdivo* Breakthrough Therapy Designation in May 2014 for the treatment of patients with Hodgkin lymphoma after failure of autologous stem cell transplant and brentuximab. On July 4, ONO PHARMACEUTICAL CO. announced that *Opdivo* received manufacturing and marketing approval in Japan for the treatment of patients with unresectable melanoma, making *Opdivo* the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world. On September 26, Bristol-Myers Squibb announced that the FDA accepted for priority review the Biologics License Application for previously treated advanced melanoma, and the Prescription Drug User Fee Act (PDUFA) goal date for a decision is March 30, 2015. The FDA also granted *Opdivo* Breakthrough Therapy status for this indication. In the European Union, the European Medicines Agency (EMA) has validated for review the Marketing Authorization Application (MAA) for

Opdivo in advanced melanoma and lung cancer. The advanced melanoma application has also been granted accelerated assessment by the EMA's Committee for Medicinal Products for Human Use (CHMP).

About Lung Cancer

Lung cancer is the leading cause of cancer deaths globally, resulting in more than 1.5 million deaths each year according the World Health Organization. NSCLC is one of the most common types of the disease and accounts for approximately 85 percent of cases. Survival rates vary depending on the stage and type of the cancer when it is diagnosed. Globally, the five-year survival rate for Stage I NSCLC is between 47 and 50 percent; for Stage IV NSCLC, the five-year survival rate drops to two percent. Historically, the expected one-year survival rate for third-line squamous cell NSCLC patients is approximately 5.5% - 18%.[i, ii]

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 Bristol-Myers Squibb and ONO PHARMACEUTICAL Collaboration

In 2011, through a collaboration agreement with ONO PHARMACEUTICAL CO., 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, Bristol-Myers Squibb and ONO PHARMACEUTICAL 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 pharmaceutical 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.

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 Opdivo will receive regulatory approval in the U.S. or, if approved, that it will become a commercially successful product. 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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[i] Massarelli E, et al. *Lung Cancer* 2003;39: 55-61
[ii] Penrod JR, et al. Poster presentation at ASCO 2014. Poster 45