March 2, 2016

Bristol-Myers Squibb Receives Two Positive CHMP Opinions for Opdivo® (nivolumab) for Patients with Previously Treated Advanced Non-Squamous Non-Small Cell Lung Cancer and Renal Cell Carcinoma

(PRINCETON, NJ, February 26**,** 2016) **–** Bristol-Myers Squibb Company (NYSE: BMY) announced that the Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of Opdivo (nivolumab) for two new indications – adults with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) after prior chemotherapy, and adults with advanced renal cell carcinoma (RCC) after prior therapy. Both indications are supported by Phase 3 studies in which Opdivo demonstrated a survival benefit versus a standard of care. The CHMP positive opinions will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU). Opdivo is already approved by the EC for advanced melanoma and previously treated advanced squamous NSCLC.

Bristol-Myers Squibb (BMS) has a robust clinical development program in Opdivo monotherapy and in combination therapy with other therapeutic drugs in a variety of tumor types overseas, including Head and Neck Cancer, Glioblastoma, Small Cell Lung Cancer, Urothelial Cancer, Hepatocellular Carcinoma, Esophageal Cancer, Hodgkin Lymphoma, Colorectal Cancer, Solid Tumors (Triple-Negative Breast Cancer, Gastric Cancer, Pancreatic Cancer), Blood Cancer, etc. In Japan, Ono Pharmaceutical Co., Ltd. (ONO) launched Opdivo for the treatment of unresectable melanoma in September 2014. ONO received an approval for additional indication of unresectable, advanced or recurrent non-small cell lung cancer in December 2015. ONO is also conducting clinical development program including Renal Cell Cancer, Head and Neck Cancer, Gastric Cancer, Esophageal Cancer, Small Cell Lung Cancer, Hepatocellular Carcinoma, Glioblastoma, Ovarian Cancer, Hodgkin Lymphoma, Urothelial Cancer, Biliary Tract Cancer, etc.

In Japan, ONO and BMS (and BMS Japan subsidiary BMKK) have formed a strategic partnership that includes co-development, co-commercialization, and co-promotion of multiple immunotherapies for patients with cancer.

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

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Bristol-Myers Squibb Receives Two Positive CHMP Opinions for *Opdivo*® (nivolumab) for Patients with Previously Treated Advanced Non-Squamous Non-Small Cell Lung Cancer and Renal Cell Carcinoma

CHMP recommends expanding the existing lung indication for Opdivo *to include previously treated metastatic non-squamous non-small cell lung cancer patients, regardless of PD-L1 expression*

CHMP recommends Opdivo *in previously treated advanced renal cell carcinoma patients based on the study, CheckMate -025, demonstrating an overall survival benefit*

(PRINCETON, NJ, February 26**,** 2016) **–** Bristol-Myers Squibb Company (NYSE: BMY) today announced that the Committee for Medicinal Products for Human Use (CHMP) has recommended the approval of *Opdivo* (nivolumab) for two new indications – adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) after prior chemotherapy, and adults with advanced renal cell carcinoma (RCC) after prior therapy. Both indications are supported by Phase 3 studies in which *Opdivo* demonstrated a survival benefit versus a standard of care. The CHMP positive opinions will now be reviewed by the European Commission (EC), which has the authority to approve medicines for the European Union (EU). *Opdivo* is already approved by the EC for advanced melanoma and previously treated advanced squamous NSCLC.

Michael Giordano, M.D., senior vice president, head of Development, Oncology, Bristol-Myers Squibb, commented, “We are committed to advancing our mission to make *Opdivo* available to a broader range of patients with a wide range of cancers who are in critical need of new treatment options. Today’s two positive CHMP opinions are important achievements and mean we are closer to reaching this goal for those with advanced non-squamous non-small cell lung cancer and renal cell carcinoma. We look forward to the European Commission's decision and the opportunity to bring an additional treatment option to these patients as quickly as possible."

In lung cancer, the CHMP adopted the positive opinion based on a review of the global Phase 3 study, CheckMate -057, which evaluated the survival of patients with non-squamous NSCLC who had progressed during or after one prior platinum doublet-based chemotherapy regimen. In the trial, *Opdivo* demonstrated superior overall survival (OS) in previously treated metastatic non-squamous NSCLC compared to chemotherapy, with a 27% reduction in the risk of death (HR: 0.73 [95% CI: 0.59, 0.89; p=0.0015]), based on a prespecified interim analysis. The median OS was 12.2 months in the *Opdivo*

arm (95% CI: 9.7, 15.0) and 9.4 months in the docetaxel arm (95% CI: 8.0, 10.7). Fifty-one percent of patients were alive at one year in the *Opdivo* arm (95% CI: 45-56) vs. 39% in the docetaxel arm (95% CI: 33-45). The safety profile of *Opdivo* in CheckMate -057 was consistent with prior studies. In the overall patient population, which included both PD-L1 expressors and non-expressors, the most frequent serious adverse reactions in at least 2% of patients receiving *Opdivo* were pneumonia, pulmonary embolism, dyspnea, pleural effusions and respiratory failure. The most common adverse reactions in patients treated with *Opdivo* (reported in >20% of patients) were fatigue (49%), musculoskeletal pain (36%), cough (30%), decreased appetite (29%) and constipation (23%).

In renal cell carcinoma, the CHMP adopted the positive opinion based on a review of the Phase 3 study, CheckMate -025, which evaluated *Opdivo* versus everolimus in patients with advanced clear-cell RCC after prior therapy, with OS as the primary endpoint. Patients treated with *Opdivo* in this study achieved a more than five month improvement in OS with median OS of 25 months for *Opdivo* and 19.6 months for everolimus (hazard ratio: 0.73; [98.5% CI, 0.57-0.93; p=0.0018]), with OS benefit seen regardless of PD-L1 expression. *Opdivo* is the first and only anti-PD-1 therapy to demonstrate a significant survival benefit in this population through a randomized Phase 3 study. In addition, patients treated with *Opdivo* also experienced a significant improvement in their health-related quality of life and had significantly lower symptom burden compared to patients receiving everolimus. The safety profile of *Opdivo* in CheckMate -025 was consistent with prior studies. Serious adverse events occurred in 47% of patients receiving *Opdivo.* The most frequent serious adverse reactions reported in at least 2% of patients receiving *Opdivo* were acute kidney injury, pleural effusion, pneumonia, diarrhea, and hypercalcemia. In the study, the most common adverse reactions in patients receiving *Opdivo* versus everolimus (reported in >20% of patients) were asthenic conditions (56% vs. 57%), cough (34% vs. 38%), nausea (28% vs. 29%), rash (28% vs. 36%), dyspnea (27% vs. 31%), diarrhea (25% vs. 32%), constipation (23% vs. 18%), decreased appetite (23% vs. 30%), back pain (21% vs. 16%), and arthralgia (20% vs. 14%).

Clinical results from CheckMate -057 and CheckMate -025 were presented at the 2015 European Cancer Congress, and published in *The New England Journal of Medicine.*

About Lung Cancer

Lung cancer is the leading cause of cancer deaths globally, resulting in more than 1.5 million deaths each year, according to the World Health Organization. Non-small cell lung cancer (NSCLC) is one of the most common types of the disease and accounts for approximately 85% of cases. About 25% to 30% of all lung cancers are squamous cell carcinomas, and non-squamous NSCLC accounts for

approximately 50% to 65% of all lung cancer 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%; for Stage IV NSCLC, the five-year survival rate drops to 2%.

About Renal Cell Carcinoma

Renal cell carcinoma (RCC) is the most common type of kidney cancer in adults, accounting for more than 100,000 deaths worldwide each year. Clear-cell RCC is the most prevalent type of RCC and constitutes 80% to 90% of all cases. RCC is approximately twice as common in men as in women, with the highest rates of the disease in North America and Europe. Globally, the five-year survival rate for those diagnosed with metastatic, or advanced kidney cancer, is 12.1%.

Bristol-Myers Squibb & Immuno-Oncology: Advancing Oncology Research

At Bristol-Myers Squibb, we have a vision for the future of cancer care that is focused on Immuno-Oncology, now considered a major treatment choice alongside surgery, radiation, chemotherapy and targeted therapies for certain types of cancer.

We have a comprehensive clinical portfolio of investigational and approved Immuno-Oncology agents, many of which were discovered and developed by our scientists. Our ongoing Immuno-Oncology clinical program is looking at broad patient populations, across multiple solid tumors and hematologic malignancies, and lines of therapy and histologies, with the intent of powering our trials for overall survival and other important measures like durability of response. We pioneered the research leading to the first regulatory approval for the combination of two Immuno-Oncology agents, and continue to study the role of combinations in cancer.

We are also investigating other immune system pathways in the treatment of cancer including CTLA-4, CD-137, KIR, SLAMF7, PD-1, GITR, CSF1R, IDO, and LAG-3. These pathways may lead to potential new treatment options – in combination or monotherapy – to help patients fight different types of cancers.

Our collaboration with academia, as well as small and large biotech companies is responsible for researching the potential Immuno-Oncology and non-Immuno-Oncology combinations, with the goal of providing new treatment options in clinical practice.

At Bristol-Myers Squibb, we are committed to changing survival expectations in hard-to-treat cancers and the way patients live with cancer.

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 a PD-1 immune checkpoint inhibitor that binds to the checkpoint receptor PD-1 expressed on activated T-cells, and blocks the binding of PD-L1 and PD-L2, preventing the PD-1 pathway's suppressive signaling on the immune system, including the interference with an anti-tumor immune response.

Opdivo's broad global development program is based on Bristol-Myers Squibb's understanding of the biology behind Immuno-Oncology. Our company is at the forefront of researching the potential of Immuno-Oncology to extend survival in hard-to-treat cancers. This scientific expertise serves as the basis for the *Opdivo* development program, which includes a broad range of Phase 3 clinical trials evaluating overall survival as the primary endpoint across a variety of tumor types. The *Opdivo* trials have also contributed toward the clinical and scientific understanding of the role of biomarkers and how patients may benefit from *Opdivo* across the continuum of PD-L1 expression. To date, the *Opdivo* clinical development program has enrolled more than 18,000 patients.

Opdivo was the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world in July 2014, and currently has regulatory approval in 46 countries including the United States, Japan, and in the European Union.

U.S. FDA APPROVED INDICATIONS

OPDIVO® (nivolumab) is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO.

OPDIVO® (nivolumab) is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

IMPORTANT SAFETY INFORMATION

Immune-Mediated Pneumonitis

Immune-mediated pneumonitis, including fatal cases, occurred with OPDIVO treatment. Across the clinical trial experience with solid tumors, fatal immune-mediated pneumonitis occurred with OPDIVO. Monitor patients for signs with radiographic imaging and symptoms of pneumonitis. Administer corticosteroids for Grade 2 or greater pneumonitis. Permanently discontinue for Grade 3 or 4 and withhold until resolution for Grade 2. In Checkmate 057, immune-mediated pneumonitis, including interstitial lung disease, occurred in 3.4% (10/287) of patients: Grade 3 (n=5), Grade 2 (n=2), and Grade 1 (n=3). In Checkmate 025, pneumonitis, including interstitial lung disease, occurred in 5% (21/406) of

patients receiving OPDIVO and 18% (73/397) of patients receiving everolimus. Immune-mediated pneumonitis occurred in 4.4% (18/406) of patients receiving OPDIVO: Grade 4 (n=1), Grade 3 (n=4), Grade 2 (n=12), and Grade 1 (n=1).

Immune-Mediated Colitis

Immune-mediated colitis can occur with OPDIVO treatment. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 (of more than 5 days duration), 3, or 4 colitis. As a single agent, withhold OPDIVO for Grade 2 or 3 and permanently discontinue for Grade 4 or recurrent colitis upon restarting OPDIVO. In Checkmate 057, diarrhea or colitis occurred in 17% (50/287) of patients receiving OPDIVO. Immune-mediated colitis occurred in 2.4% (7/287) of patients: Grade 3 (n=3), Grade 2 (n=2), and Grade 1 (n=2). In Checkmate 025, diarrhea or colitis occurred in 25% (100/406) of patients receiving OPDIVO and 32% (126/397) of patients receiving everolimus. Immune-mediated diarrhea or colitis occurred in 3.2% (13/406) of patients receiving OPDIVO: Grade 3 (n=5), Grade 2 (n=7), and Grade 1 (n=1).

Immune-Mediated Hepatitis

Immune-mediated hepatitis can occur with OPDIVO treatment. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater transaminase elevations. Withhold for Grade 2 and permanently discontinue for Grade 3 or 4 immune-mediated hepatitis. In Checkmate 057, one patient (0.3%) developed immune-mediated hepatitis. In Checkmate 025, there was an increased incidence of liver test abnormalities compared to baseline in AST (33% vs 39%), alkaline phosphatase (32% vs 32%), ALT (22% vs 31%), and total bilirubin (9% vs 3.5%) in the OPDIVO and everolimus arms, respectively. Immune-mediated hepatitis requiring systemic immunosuppression occurred in 1.5% (6/406) of patients receiving OPDIVO: Grade 3 (n=5) and Grade 2 (n=1).

Immune-Mediated Endocrinopathies

Hypophysitis, adrenal insufficiency, thyroid disorders, and type 1 diabetes mellitus can occur with OPDIVO treatment. Monitor patients for signs and symptoms of hypophysitis, signs and symptoms of adrenal insufficiency during and after treatment, thyroid function prior to and periodically during treatment, and hyperglycemia. Administer corticosteroids for Grade 2 or greater hypophysitis. Withhold for Grade 2 or 3 and permanently discontinue for Grade 4 hypophysitis. Administer corticosteroids for Grade 3 or 4 adrenal insufficiency. Withhold for Grade 2 and permanently discontinue for Grade 3 or 4 adrenal insufficiency. Administer hormone-replacement therapy for hypothyroidism. Initiate medical management for control of hyperthyroidism. Administer insulin for type 1 diabetes. Withhold OPDIVO for Grade 3 and permanently discontinue for Grade 4 hyperglycemia.

In Checkmate 025, hypophysitis occurred in 0.5% (2/406) of patients receiving OPDIVO: Grade 3 (n=1) and Grade 1 (n=1). In Checkmate 057, 0.3% (1/287) of OPDIVO-treated patients developed adrenal insufficiency. In Checkmate 025, adrenal insufficiency occurred in 2.0% (8/406) of patients receiving OPDIVO: Grade 3 (n=3), Grade 2 (n=4), and Grade 1 (n=1). In Checkmate 057, Grade 1 or 2 hypothyroidism, including thyroiditis, occurred in 7% (20/287) and elevated thyroid stimulating hormone occurred in 17% of patients receiving OPDIVO. Grade 1 or 2 hyperthyroidism occurred in

1.4% (4/287) of patients. In Checkmate 025, thyroid disease occurred in 11% (43/406) of patients receiving OPDIVO, including one Grade 3 event, and in 3.0% (12/397) of patients receiving everolimus. Hypothyroidism/thyroiditis occurred in 8% (33/406) of patients receiving OPDIVO: Grade 3 (n=2), Grade 2 (n=17), and Grade 1 (n=14). Hyperthyroidism occurred in 2.5% (10/406) of patients receiving OPDIVO: Grade 2 (n=5) and Grade 1 (n=5). In Checkmate 025, hyperglycemic adverse events occurred in 9% (37/406) patients. Diabetes mellitus or diabetic ketoacidosis occurred in 1.5% (6/406) of patients receiving OPDIVO: Grade 3 (n=3), Grade 2 (n=2), and Grade 1 (n=1).

Immune-Mediated Nephritis and Renal Dysfunction

Immune-mediated nephritis can occur with OPDIVO treatment. Monitor patients for elevated serum creatinine prior to and periodically during treatment. For Grade 2 or 3 increased serum creatinine, withhold and administer corticosteroids; if worsening or no improvement occurs, permanently discontinue. Administer corticosteroids for Grade 4 serum creatinine elevation and permanently discontinue. In Checkmate 057, Grade 2 immune-mediated renal dysfunction occurred in 0.3% (1/287) of patients receiving OPDIVO. In Checkmate 025, renal injury occurred in 7% (27/406) of patients receiving OPDIVO and 3.0% (12/397) of patients receiving everolimus. Immune-mediated nephritis and renal dysfunction occurred in 3.2% (13/406) of patients receiving OPDIVO: Grade 5 (n=1), Grade 4 (n=1), Grade 3 (n=5), and Grade 2 (n=6).

Immune-Mediated Rash

Immune-mediated rash can occur with OPDIVO treatment. Severe rash (including rare cases of fatal toxic epidermal necrolysis) occurred in the clinical program of OPDIVO. Monitor patients for rash. Administer corticosteroids for Grade 3 or 4 rash. Withhold for Grade 3 and permanently discontinue for Grade 4. In Checkmate 057, immune-mediated rash occurred in 6% (17/287) of patients receiving OPDIVO including four Grade 3 cases. In Checkmate 025, rash occurred in 28% (112/406) of patients receiving OPDIVO and 36% (143/397) of patients receiving everolimus. Immune-mediated rash, defined as a rash treated with systemic or topical corticosteroids, occurred in 7% (30/406) of patients receiving OPDIVO: Grade 3 (n=4), Grade 2 (n=7), and Grade 1 (n=19).

Immune-Mediated Encephalitis

Immune-mediated encephalitis can occur with OPDIVO treatment. Withhold OPDIVO in patients with new-onset moderate to severe neurologic signs or symptoms and evaluate to rule out other causes. If other etiologies are ruled out, administer corticosteroids and permanently discontinue OPDIVO for immune-mediated encephalitis. In Checkmate 057, fatal limbic encephalitis occurred in one patient (0.3%) receiving OPDIVO.

Other Immune-Mediated Adverse Reactions

Based on the severity of adverse reaction, permanently discontinue or withhold treatment, administer high-dose corticosteroids, and, if appropriate, initiate hormone-replacement therapy. In < 1.0% of patients receiving OPDIVO, the following clinically significant, immune-mediated adverse reactions occurred: uveitis, pancreatitis, facial and abducens nerve paresis, demyelination, polymyalgia

rheumatica, autoimmune neuropathy, Guillain-Barré syndrome, hypopituitarism, systemic inflammatory response syndrome, gastritis, duodenitis, and sarcoidosis. Across clinical trials of OPDIVO as a single agent administered at doses of 3 mg/kg and 10 mg/kg, additional clinically significant, immune-mediated adverse reactions were identified: motor dysfunction, vasculitis, and myasthenic syndrome.

Infusion Reactions

Severe infusion reactions have been reported in <1.0% of patients in clinical trials of OPDIVO. Discontinue OPDIVO in patients with Grade 3 or 4 infusion reactions. Interrupt or slow the rate of infusion in patients with Grade 1 or 2. In Checkmate 057, Grade 2 infusion reactions requiring corticosteroids occurred in 1.0% (3/287) of patients receiving OPDIVO. In Checkmate 025, hypersensitivity/infusion-related reactions occurred in 6% (25/406) of patients receiving OPDIVO and 1.0% (4/397) of patients receiving everolimus.

Embryo-fetal Toxicity

Based on its mechanism of action, OPDIVO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with an OPDIVO- containing regimen and for at least 5 months after the last dose of OPDIVO.

Lactation

It is not known whether OPDIVO is present in human milk. Because many drugs, including antibodies, are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from an OPDIVO-containing regimen, advise women to discontinue breastfeeding during treatment.

Serious Adverse Reactions

In Checkmate 057, serious adverse reactions occurred in 47% of patients receiving OPDIVO. The most frequent serious adverse reactions reported in ≥2% of patients were pneumonia, pulmonary embolism, dyspnea, pleural effusion, and respiratory failure. In Checkmate 025, serious adverse reactions occurred in 47% of patients receiving OPDIVO. The most frequent serious adverse reactions reported in ≥2% of patients were acute kidney injury, pleural effusion, pneumonia, diarrhea, and hypercalcemia.

Common Adverse Reactions

In Checkmate 057, the most common adverse reactions (≥20%) reported with OPDIVO were fatigue (49%), musculoskeletal pain (36%), cough (30%), decreased appetite (29%), and constipation (23%). In Checkmate 025, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO vs everolimus were asthenic conditions (56% vs 57%), cough (34% vs 38%), nausea (28% vs 29%), rash (28% vs 36%), dyspnea (27% vs 31%), diarrhea (25% vs 32%), constipation (23% vs 18%), decreased appetite (23% vs 30%), back pain (21% vs 16%), and arthralgia (20% vs 14%).

About the Bristol-Myers Squibb and Ono Pharmaceutical Co., Ltd. Collaboration

In 2011, through a collaboration agreement with Ono Pharmaceutical Co., Ltd (Ono) 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 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, and YouTube.

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 European Union for the indication 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, 2015 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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