April 8, 2016

European Commission Approves Bristol-Myers Squibb's *Opdivo*® (nivolumab) for Previously Treated Advanced Renal Cell Carcinoma

(PRINCETON, NJ, April 6, 2016) – Bristol-Myers Squibb Company (NYSE: BMY) announced that the European Commission has approved Opdivo (nivolumab) monotherapy for an additional indication in advanced renal cell carcinoma (RCC) after prior therapy in adults. Opdivo is the first and only PD-1 immune checkpoint inhibitor approved in Europe to demonstrate an overall survival (OS) benefit versus a standard of care in this patient population. This approval allows for the expanded marketing of Opdivo in previously treated advanced RCC in all 28 Member States of the European Union.

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. In addition, ONO has submitted supplemental applications for additional indications of Renal Cell Cancer and Hodgkin Lymphoma, and is conducting clinical development program including Head and Neck Cancer, Gastric Cancer, Esophageal Cancer, Small Cell Lung Cancer, Hepatocellular Carcinoma, Glioblastoma, Ovarian Cancer, Urothelial Cancer, Biliary Tract Cancer, etc.

In Japan, ONO and BMS (and BMS Japan subsidiary BMSKK) 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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European Commission Approves Bristol-Myers Squibb's *Opdivo*® (nivolumab) for Previously Treated Advanced Renal Cell Carcinoma

Opdivo *is the first and only PD-1 inhibitor approved to treat advanced renal cell carcinoma patients who have received prior therapy*

Opdivo is the first-ever agent to demonstrate a significant improvement in overall survival, the primary endpoint, in advanced renal cell carcinoma patients who have received prior therapy vs. everolimus, based on Phase 3 study CheckMate -025

With this approval, Opdivo *is the only PD-1 inhibitor approved in Europe to demonstrate overall survival benefit versus standards of care in three distinct tumor types*

(PRINCETON, NJ, April 6**,** 2016) **–** Bristol-Myers Squibb Company (NYSE: BMY) announced today that the European Commission has approved *Opdivo* (nivolumab) monotherapy for an additional indication in advanced renal cell carcinoma (RCC) after prior therapy in adults. *Opdivo* is the first and only PD-1 immune checkpoint inhibitor approved in Europe to demonstrate an overall survival (OS) benefit versus a standard of care in this patient population. This approval allows for the expanded marketing of *Opdivo* in previously treated advanced RCC in all 28 Member States of the European Union.

Emmanuel Blin, senior vice president, Head of Commercialization, Policy and Operations, Bristol-Myers Squibb, commented, "Today's approval is reflective of our commitment to bring *Opdivo* and the potential for long-term survival to broad patient populations, including previously treated advanced renal cell carcinoma. *Opdivo* is the only PD-1 inhibitor approved in Europe to demonstrate a significant survival advantage in this patient population. At Bristol-Myers Squibb, we are driven to work with speed to deliver new treatment options to help more patients, and in less than a year, we have expanded the approval of *Opdivo* in Europe to include three distinct types of advanced cancer."

This approval is based on the results of the Phase 3 study CheckMate -025, which were published in *The New England Journal of Medicine*. In CheckMate -025, *Opdivo* was evaluated in patients with advanced clear-cell RCC who received prior anti-angiogenic therapy compared to everolimus. Patients treated with *Opdivo* achieved a median OS of 25 months versus 19.6 months for everolimus (HR: 0.73 [98.5% CI: 0.57-0.93; p=0.0018]), representing a greater than five month improvement over a current standard of care. CheckMate -025 also evaluated patients' quality of life

(QoL) and found that patients treated with *Opdivo* had improved survival and quality of life compared to everolimus throughout the duration of treatment.

Dr. Bernard Escudier, Chair of the Genitourinary Oncology Committee, Institut Gustave Roussy in Villejuif, France, commented, "For the first time, previously treated advanced renal cell carcinoma patients in Europe will now have access to an Immuno-Oncology agent that has demonstrated a significant overall survival benefit along with a favorable safety profile compared to everolimus. In addition to the clinical efficacy results, patients treated with *Opdivo* experienced an improvement in their health-related quality of life and had significantly lower symptom burden throughout treatment compared to patients receiving everolimus. Combined, these data support the use of *Opdivo* in clinical practice and represent important progress toward establishing a new standard of care in Europe."

First PD-1 Inhibitor to Demonstrate Significant Overall Survival Benefit In Previously Treated Advanced RCC

CheckMate -025 is an open-label, randomized Phase 3 study, which evaluated *Opdivo* versus everolimus in patients with advanced clear-cell renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy, with overall survival (OS) as the primary endpoint. Objective response rate (ORR) was evaluated as a secondary endpoint. In the study, patients were randomized to receive *Opdivo* (3 mg/kg administered intravenously every two weeks) compared to everolimus (10 mg administered orally daily). The prespecified interim analysis was conducted when 398 events were observed (70% of the planned number of events for final analysis).

Results from CheckMate -025 showed that patients treated with *Opdivo* achieved a more than five month improvement in OS, with median OS of 25 months for *Opdivo* and 19.6 months for everolimus (HR: 0.73 [98.5% CI: 0.57-0.93; p=0.0018]). An OS benefit was seen regardless of PD-L1 expression. In addition to improving overall survival, *Opdivo* demonstrated a superior ORR compared to everolimus (25.1% [95% CI: 21-29.6] vs. 5.4% [95% CI: 3.4-8.0]). Forty-nine (47.6%) *Opdivo* responders had ongoing responses of up to 27.6 months.

In addition to the OS benefit observed with *Opdivo*, patients treated with the drug also experienced an improvement over time in disease related symptoms and non-disease specific quality of life (QoL) compared to patients receiving everolimus. Patients were assessed using validated and reliable scales in the Functional Assessment of Cancer Therapy-Kidney Symptom Index-Disease Related Symptoms (FKSI-DRS) and the EuroQoL EQ-5D. Results showed that as early as week 20,

patients receiving *Opdivo* had a significant improvement in disease related symptoms, while patients receiving everolimus showed a significant deterioration by week 4.

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 (≥20%) reported in patients receiving *Opdivo* versus 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 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 OS 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, to research the potential of Immuno-Oncology and non-Immuno-Oncology combinations, helps achieve our 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 OS 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 48 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 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 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 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 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). 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). 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). 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 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 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.

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 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 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 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. 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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