April 22, 2016

First Presentation of Two-Year Overall Survival Data for *Opdivo*® (nivolumab) in Combination with *Yervoy*® (ipilimumab) Showed Superior Efficacy Versus *Yervoy* Alone in Advanced Melanoma

(PRINCETON, NJ, April 17, 2016) - Bristol-Myers Squibb (NYSE: BMY) announced first time presentation of overall survival data from CheckMate -069, a Phase 2 trial and the first randomized study to evaluate the *Opdivo* and *Yervoy* combination regimen in patients with previously untreated advanced melanoma. In the trial, the *Opdivo* and *Yervoy* combination regimen demonstrated a two-year overall survival (OS) rate of 69% compared to 53% for *Yervoy* alone (HR=0.58 [95% CI: 0.31-1.08]) in patients with *BRAF* wild-type advanced melanoma. Overall survival was an exploratory endpoint in this trial. The safety profile of the *Opdivo* and *Yervoy* combination regimen in this study was consistent with previously reported studies. These data will be presented today as an oral presentation at the American Association for Cancer Research (AACR) 2016 Annual Meeting during the Immuno-Oncology Clinical Trials I Plenary Session from 2:15 – 4:00 P.M. CT in New Orleans, Louisiana (Late-Breaking and Clinical Trial Abstract #CT002).

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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Bristol-Myers Squibb

First Presentation of Two-Year Overall Survival Data for *Opdivo*® (nivolumab) in Combination with *Yervoy*® (ipilimumab) Showed Superior Efficacy Versus *Yervoy* Alone in Advanced Melanoma

Opdivo *and* Yervoy *combination regimen showed two-year overall survival rate of 69% in an exploratory analysis of patients with BRAF wild-type advanced melanoma in CheckMate -069; with 22% of patients achieving a complete response*

Safety profile of the combination regimen from CheckMate -069 was consistent with previously reported studies and adverse events were managed using established safety algorithms

Data from study CA209-003, also to be presented, showed a five-year overall survival rate of 34% with Opdivo *monotherapy in heavily pretreated advanced melanoma patients*

(PRINCETON, NJ, April 17, 2016) - Bristol-Myers Squibb Company (NYSE: BMY) announced today first time presentation of overall survival data from CheckMate -069, a Phase 2 trial and the first randomized study to evaluate the *Opdivo* and *Yervoy* combination regimen in patients with previously untreated advanced melanoma. In the trial, the *Opdivo* and *Yervoy* combination regimen demonstrated a two-year overall survival (OS) rate of 69% compared to 53% for *Yervoy* alone (HR=0.58 [95% CI: 0.31-1.08]) in patients with *BRAF* wild-type advanced melanoma. Overall survival was an exploratory endpoint in this trial. The safety profile of the *Opdivo* and *Yervoy* combination regimen in this study was consistent with previously reported studies. These data will be presented today as an oral presentation at the American Association for Cancer Research (AACR) 2016 Annual Meeting during the Immuno-Oncology Clinical Trials I Plenary Session from 2:15 – 4:00 P.M. CT in New Orleans, Louisiana (Late-Breaking and Clinical Trial Abstract #CT002).

Bristol-Myers Squibb is also presenting extended follow-up data, including five-year OS rates, from the Phase 1 dose escalation study, CA209-003, evaluating *Opdivo* monotherapy in heavily pretreated advanced melanoma patients. These data represent the longest survival follow-up of patients who received an anti-PD-1 therapy in a clinical trial. At five years, patients who received *Opdivo* showed an OS rate of 34%, with an evident plateau in survival at approximately four years. The safety profile of *Opdivo* in study -003 was similar to previously reported studies, with no new safety signals identified. These data were featured during the Congress' official press program today at 12:30 P.M. CT, and will be presented as an oral presentation during the Immuno-Oncology Clinical Trials I Plenary Session from 2:15 – 4:00 P.M. CT (Late-Breaking and Clinical Trial Abstract #CT001).

"The data from CheckMate -069 and study -003 showed durable responses for some patients with advanced melanoma using new Immuno-Oncology approaches. These data contribute to our growing understanding of this aggressive cancer and are promising news for advanced melanoma patients. In particular, we are seeing further data that evaluate the potential survival benefit of the nivolumab and ipilimumab combination," said F. Stephen Hodi, M.D., director of the Melanoma Center at Dana-Farber Cancer Institute and associate professor of medicine at Harvard Medical School.

Melanoma continues to be the most aggressive and deadliest form of skin cancer, with an increase in global incidence rates over the last 30 years. Despite advances in treatment, patients with advanced stages of the disease have lower survival rates, with a five-year survival of 15% - 20% for Stage IV disease.

Jean Viallet, M.D., Global Clinical Research Lead, Oncology, Bristol-Myers Squibb, commented, "We are encouraged to see that the *Opdivo* and *Yervoy* combination showed improvement in overall survival versus *Yervoy* alone based on two-year follow-up from CheckMate -069, the registrational study of the combination regimen. These data further validate our scientific rationale for studying the combination of these Immuno-Oncology agents. Additionally, study -003 shows five-year overall survival with *Opdivo* monotherapy in heavily pretreated advanced melanoma patients. These data provide important information about the possible role of *Opdivo* as a single agent in improving long-term survival for these patients."

About CheckMate -069

CheckMate -069 is a Phase 2, double-blind, randomized study which evaluated 142 patients with previously untreated unresectable or metastatic melanoma who received either the *Opdivo* and *Yervoy* combination regimen (n=95) or *Yervoy* alone (n=47). The trial included patients with *BRAF* wild-type and *BRAF* V600 mutation-positive melanoma, and randomization was stratified by *BRAF* mutation status. The primary endpoint was objective response rate (ORR) in patients with *BRAF* wild-type tumors. Secondary endpoints included progression-free survival (PFS) in patients with *BRAF* wild-type tumors, ORR in patients with *BRAF* V600 mutation positive tumors, and safety. Overall survival (OS) was an exploratory endpoint.

In the trial, the combination of *Opdivo* and *Yervoy* demonstrated a clinically meaningful improvement in survival at two years with an OS rate of 69% compared to 53% for *Yervoy* alone in patients with *BRAF* wild-type advanced melanoma (HR=0.58 [95% CI: 0.31-1.08]), with a minimum follow-up of 24 months. Similar results were observed in the overall study population, with an OS rate of 64% at two years for the *Opdivo* and *Yervoy* combination regimen compared to 54% for *Yervoy* alone

(HR=0.74 [95% CI: 0.43-1.26]). Per the study protocol, patients who did not respond to treatment or experienced disease progression after treatment received subsequent therapies, including 55% of patients in the *Yervoy* monotherapy arm who crossed over to receive *Opdivo* monotherapy. A change in tumor burden was seen with the *Opdivo* and *Yervoy* combination regimen, with a median change of 70% decrease in tumor burden compared to a 5% increase for *Yervoy* alone.

At two years of follow-up, median duration of response was not reached in both arms, with ongoing responses seen in 80% of responders. Progression-free survival at two years was significantly longer with the *Opdivo* and *Yervoy* combination regimen (n=72) compared to *Yervoy* alone (n=37). In patients with *BRAF* wild-type advanced melanoma, median PFS has not been reached (8.6-NR) compared to 4.4 months (2.8-5.3) for *Yervoy* alone (HR=0.35 [95% CI: 0.21-0.59; $p<0.0001$]), with a two-year PFS rate of 54% with the *Opdivo* and *Yervoy* combination regimen vs. 11% for *Yervoy* alone. In all randomized patients, median PFS has also not been reached (7.36-NR) in patients treated with the *Opdivo* and *Yervoy* combination regimen vs. 3.0 months (2.7-5.1) for patients treated with *Yervoy* alone, with a two-year PFS rate of 51% vs. 12%, respectively. Similar efficacy was seen regardless of PD-L1 expression at 5% across endpoints with the *Opdivo* and *Yervoy* combination regimen.

As reported last year at AACR, and with a minimum follow-up of 11 months, the *Opdivo* and *Yervoy* combination regimen demonstrated improved ORR in both *BRAF* wild-type and *BRAF* V600 mutation-positive advanced melanoma compared to *Yervoy* alone. In patients with *BRAF* wild-type advanced melanoma, ORR in the combination regimen arm was 61% with 22% of patients achieving a complete response and 39% achieving a partial response, compared to 11% ORR in the *Yervoy* monotherapy arm with 0% of patients achieving a complete response and 11% of patients achieving a partial response. In all randomized patients, ORR in the combination regimen arm was 59% with 22% of patients achieving a complete response and 37% of patients achieving a partial response, compared to 11% in the *Yervoy* monotherapy arm with 0% of patients achieving a complete response and 11% of patients achieving a partial response.

The safety profile of the combination of *Opdivo* and *Yervoy* in this updated analysis of CheckMate -069 was consistent with previously reported studies and most treatment-related select adverse events (AEs) were treated with immune-modulating medications. The majority (>85%) of treatment-related select AEs were managed when immune-modulating medications were utilized, except for endocrinopathies. Grade 3-4 treatment-related AEs were reported more frequently with the combination regimen (54%) than with *Yervoy* alone (20%). Treatment-related AEs of any grade led to discontinuation in 37% of patients treated with the combination regimen and 9% of patients treated with

Yervoy alone. Three treatment-related deaths occurred in the *Opdivo* and *Yervoy* combination regimen arm, which were previously-reported. The most common treatment-related select AEs of any grade with the combination regimen vs. *Yervoy* alone included rash (43% vs. 30%), pruritus (40% vs. 33%), diarrhea (45% vs. 35%), colitis (18% vs. 7%), hypothyroidism (17% vs. 13%), hypophysitis (13% vs. 7%), increased ALT (26% vs. 9%), increased AST (28% vs. 9%), pneumonitis (10% vs. 2%), and increased creatinine (2% vs. 0%).

About Study CA209-003

CA209-003, or study -003, is a Phase 1b, open-label, multicenter, multidose, dose-escalation study of *Opdivo* in patients with select advanced or recurrent malignancies, including previously treated melanoma. In this study, *Yervoy*-naïve patients who had received one to five prior systemic therapies for advanced melanoma (n=107) were treated with *Opdivo* (0.1, 0.3, 1, 3 or 10 mg/kg) every two weeks for <96 weeks. Patients were followed for overall survival (OS), progression-free survival (PFS), long-term safety, and response duration after discontinuing treatment.

At five years, the OS rate for patients treated with *Opdivo* was 34% (95% CI: 25-43), with a median OS of 17.3 months (95% CI: 12.5-37.8), with a minimum follow-up of 45 months. In patients treated with *Opdivo* 3 mg/kg, median OS was 20.3 months (95% CI: 7.2-NR), with an OS rate of 35% at five years. At the last timepoint for tumor assessment, PFS rates at 30 months were 26% for patients who received *Opdivo* at 3 mg/kg, and 19% for all patients receiving *Opdivo* at any dose. Objective response rate (ORR) for *Opdivo* 3 mg/kg was 41% with a median duration of response lasting 22 months (9-27+), and the ORR was 32% for all doses with a median duration of response lasting 23 months (4-32). Of responding patients, 44% showed a response at first tumor assessment (8 weeks), and responses are ongoing in 41% of responders (14/34).

The safety profile of *Opdivo* in study 003 was similar to previously reported studies, with no new safety signals identified. The most common treatment-related adverse events (AEs) of any grade in patients treated with *Opdivo* 3 mg/kg were fatigue (47.1%), pruritus (17.6%), dermatitis acneiform (17.6%), nausea (17.6%), lymphopenia (17.6%), infusion-related reactions (17.6%), rash (11.8%) and diarrhea (11.8%). Adverse reactions leading to discontinuation occurred in 5.9% of patients treated with *Opdivo* 3 mg/kg.

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, to research the potential 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 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 50 countries including the United States, Japan, and in the European Union.

U.S. FDA APPROVED INDICATIONS

OPDIVO® (nivolumab) as a single agent is indicated for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma.

OPDIVO® (nivolumab) as a single agent is indicated for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon demonstration of clinical benefit in confirmatory trials.

OPDIVO® (nivolumab), in combination with YERVOY® (ipilimumab), is indicated for the treatment of patients with unresectable or metastatic melanoma. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon demonstration of clinical benefit in confirmatory trials.

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

WARNING: IMMUNE-MEDIATED ADVERSE REACTIONS

YERVOY can result in severe and fatal immune-mediated adverse reactions. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of YERVOY.

Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrinopathy and evaluate clinical chemistries including liver function tests (LFTs), adrenocorticotropic hormone (ACTH) level, and thyroid function tests at baseline and before each dose.

Permanently discontinue YERVOY and initiate systemic high-dose corticosteroid therapy for severe immune-mediated reactions.

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. In addition, in Checkmate 069, there were six patients who died without resolution of abnormal respiratory findings. 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 069 and 067, immune-mediated pneumonitis occurred in 6% (25/407) of patients receiving OPDIVO with YERVOY: Fatal (n=1), Grade 3 (n=6), Grade 2 (n=17), and Grade 1 (n=1). In Checkmate 037, 066, and 067, immune-mediated pneumonitis occurred in 1.8% (14/787) of patients receiving OPDIVO: Grade 3 (n=2) and Grade 2 (n=12). 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. When administered with YERVOY, withhold OPDIVO for Grade 2 and permanently discontinue for Grade 3 or 4 or recurrent colitis upon restarting OPDIVO. In Checkmate 069 and 067, diarrhea or colitis occurred in 56% (228/407) of patients receiving OPDIVO with YERVOY. Immune-mediated colitis occurred in 26% (107/407) of patients: Grade 4 (n=2), Grade 3 (n=60), Grade 2 (n=32), and Grade 1 (n=13). In Checkmate 037, 066, and 067, diarrhea or colitis occurred in 31% (242/787) of patients receiving OPDIVO. Immune-mediated colitis occurred in 4.1% (32/787) of patients: Grade 3 (n=20), Grade 2 (n=10), and Grade 1 (n=2). 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).

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal (diarrhea of ≥7 stools above baseline, fever, ileus, peritoneal signs; Grade 3-5) immune-mediated enterocolitis occurred in 34 (7%) patients. Across all YERVOY-treated patients in that study (n=511), 5 (1%) developed intestinal perforation, 4 (0.8%) died as a result of complications, and 26 (5%) were hospitalized for severe enterocolitis.

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 069 and 067, immune-mediated hepatitis occurred in 13% (51/407) of patients receiving OPDIVO with YERVOY: Grade 4 (n=8), Grade 3 (n=37), Grade 2 (n=5), and Grade 1 (n=1). In Checkmate 037, 066, and 067, immune-mediated hepatitis occurred in 2.3% (18/787) of patients receiving OPDIVO: Grade 4 (n=3), Grade 3 (n=11), and Grade 2 (n=4). 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).

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal hepatotoxicity (AST or ALT elevations >5x the ULN or total bilirubin elevations >3x the ULN; Grade 3-5) occurred in 8 (2%) patients, with fatal hepatic failure in 0.2% and hospitalization in 0.4%.

Immune-Mediated Dermatitis

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal immune-mediated dermatitis (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis, or rash complicated by full thickness dermal ulceration, or necrotic, bullous, or hemorrhagic manifestations; Grade 3-5) occurred in 13 (2.5%) patients. 1 (0.2%) patient died as a result of toxic epidermal necrolysis. 1 additional patient required hospitalization for severe dermatitis.

Immune-Mediated Neuropathies

In a separate Phase 3 study of YERVOY 3 mg/kg, 1 case of fatal Guillain-Barré syndrome and 1 case of severe (Grade 3) peripheral motor neuropathy were reported.

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 069 and 067, hypophysitis occurred in 9% (36/407) of patients receiving OPDIVO with YERVOY: Grade 3 (n=8), Grade 2 (n=25), and Grade 1 (n=3). In Checkmate 037, 066, and 067, hypophysitis occurred in 0.9% (7/787) of patients receiving OPDIVO: Grade 3 (n=2), Grade 2 (n=3), and Grade 1 (n=2). 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 069 and 067, adrenal insufficiency occurred in 5% (21/407) of patients receiving OPDIVO with YERVOY: Grade 4 (n=1), Grade 3 (n=7), Grade 2 (n=11), and Grade 1 (n=2). In Checkmate 037, 066, and 067, adrenal insufficiency occurred in 1% (8/787) of patients receiving OPDIVO: Grade 3 (n=2), Grade 2 (n=5), 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 069 and 067, hypothyroidism or thyroiditis occurred in 22% (89/407) of patients receiving OPDIVO with YERVOY: Grade 3 (n=6), Grade 2 (n=47), and Grade 1 (n=36). Hyperthyroidism occurred in 8% (34/407) of patients: Grade 3 (n=4), Grade 2 (n=17), and Grade 1 (n=13). In Checkmate 037, 066, and 067, hypothyroidism or thyroiditis occurred in 9% (73/787) of patients receiving OPDIVO: Grade 3 (n=1), Grade 2 (n=37), Grade 1 (n=35). Hyperthyroidism occurred in 4.4% (35/787) of patients receiving OPDIVO: Grade 3 (n=1), Grade 2 (n=12), and Grade 1 (n=22). 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 069 and 067, diabetes mellitus or diabetic ketoacidosis occurred in 1.5% (6/407) of patients: Grade 4 (n=3), Grade 3 (n=1), Grade 2 (n=1), and Grade 1 (n=1). In Checkmate 037, 066, and

067, diabetes mellitus or diabetic ketoacidosis occurred in 0.8% (6/787) of patients receiving OPDIVO: Grade 3 (n=2), Grade 2 (n=3), and Grade 1 (n=1). 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).

In a separate Phase 3 study of YERVOY 3 mg/kg, severe to life-threatening immune-mediated endocrinopathies (requiring hospitalization, urgent medical intervention, or interfering with activities of daily living; Grade 3-4) occurred in 9 (1.8%) patients. All 9 patients had hypopituitarism, and some had additional concomitant endocrinopathies such as adrenal insufficiency, hypogonadism, and hypothyroidism. 6 of the 9 patients were hospitalized for severe endocrinopathies.

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 069 and 067, immune-mediated nephritis and renal dysfunction occurred in 2.2% (9/407) of patients: Grade 4 (n=4), Grade 3 (n=3), and Grade 2 (n=2). In Checkmate 037, 066, and 067, nephritis and renal dysfunction of any grade occurred in 5% (40/787) of patients receiving OPDIVO. Immune-mediated nephritis and renal dysfunction occurred in 0.8% (6/787) of patients: Grade 3 (n=4) and Grade 2 (n=2). 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 069 and 067, immune-mediated rash occurred in 22.6% (92/407) of patients receiving OPDIVO with YERVOY: Grade 3 (n=15), Grade 2 (n=31), and Grade 1 (n=46). In Checkmate 037, 066, and 067, immune-mediated rash occurred in 9% (72/787) of patients receiving OPDIVO: Grade 3 (n=7), Grade 2 (n=15), and Grade 1 (n=50). 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 067, encephalitis was identified in one patient (0.2%) receiving OPDIVO with YERVOY. 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 069 and 067, infusion- related reactions occurred in 2.5% (10/407) of patients receiving OPDIVO with YERVOY: Grade 2 (n=6) and Grade 1 (n=4). In Checkmate 037, 066, and 067, Grade 2 infusion related reactions occurred in 2.7% (21/787) of patients receiving OPDIVO: Grade 3 (n=2), Grade 2 (n=8), and Grade 1 (n=11). 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 their mechanisms of action, OPDIVO and YERVOY 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- or YERVOY-containing regimen and for at least 5 months after the last dose of OPDIVO.

Lactation

It is not known whether OPDIVO or YERVOY 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. Advise women to discontinue nursing during treatment with YERVOY and for 3 months following the final dose.

Serious Adverse Reactions

In Checkmate 067, serious adverse reactions (73% and 37%), adverse reactions leading to permanent discontinuation (43% and 14%) or to dosing delays (55% and 28%), and Grade 3 or 4 adverse reactions (72% and 44%) all occurred more frequently in the OPDIVO plus YERVOY arm relative to the

OPDIVO arm. The most frequent (≥10%) serious adverse reactions in the OPDIVO plus YERVOY arm and the OPDIVO arm, respectively, were diarrhea (13% and 2.6%), colitis (10% and 1.6%), and pyrexia (10% and 0.6%). In Checkmate 037, serious adverse reactions occurred in 41% of patients receiving OPDIVO. Grade 3 and 4 adverse reactions occurred in 42% of patients receiving OPDIVO. The most frequent Grade 3 and 4 adverse drug reactions reported in 2% to <5% of patients receiving OPDIVO were abdominal pain, hyponatremia, increased aspartate aminotransferase, and increased lipase. In Checkmate 066, serious adverse reactions occurred in 36% of patients receiving OPDIVO. Grade 3 and 4 adverse reactions occurred in 41% of patients receiving OPDIVO. The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of patients receiving OPDIVO were gamma-glutamyltransferase increase (3.9%) and diarrhea (3.4%). 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 067, the most common (≥20%) adverse reactions in the OPDIVO plus YERVOY arm were fatigue (59%), rash (53%), diarrhea (52%), nausea (40%), pyrexia (37%), vomiting (28%), and dyspnea (20%). The most common (≥20%) adverse reactions in the OPDIVO arm were fatigue (53%), rash (40%), diarrhea (31%), and nausea (28%). In Checkmate 037, the most common adverse reaction (≥20%) reported with OPDIVO was rash (21%). In Checkmate 066, the most common adverse reactions (≥20%) reported with OPDIVO vs dacarbazine were fatigue (49% vs 39%), musculoskeletal pain (32% vs 25%), rash (28% vs 12%), and pruritus (23% vs 12%). 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%).

In a separate Phase 3 study of YERVOY 3 mg/kg, the most common adverse reactions (≥5%) in patients who received YERVOY at 3 mg/kg were fatigue (41%), diarrhea (32%), pruritus (31%), rash (29%), and colitis (8%).

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 www.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 as a single agent or in combination with Yervoy will receive regulatory approval for additional indications in advanced melanoma. 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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