June 22, 2015

European Commission Approves Bristol-Myers Squibb's *Opdivo* (nivolumab), the First and Only PD-1 Checkpoint Inhibitor Approved in Europe, for Both First-Line and Previously-Treated Advanced Melanoma Patients

(PRINCETON, NJ, June 19, 2015 – Bristol-Myers Squibb Company (NYSE: BMY) announced that the European Commission has approved Opdivo, a PD-1 immune checkpoint inhibitor, for the treatment of advanced (unresectable or metastatic) melanoma in adults, regardless of BRAF status. This approval allows for the marketing of Opdivo in all 28 Member States of the EU. It follows an accelerated assessment by the Committee for Medicinal Products for Human Use (CHMP), which was announced on April 24, 2015.

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. In July 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.

In USA, Opdivo was approved under accelerated approval for the treatment of unresectable or metastatic melanoma and disease progression following Yervoy and, if BRAF V600 mutation positive, a BRAF inhibitor in December 2014 and approved for the treatment of metastatic squamous NSCLC with progression on or after platinum-based chemotherapy in March 2015. Also, BMS has a robust clinical development program in a variety of tumor types overseas, including: Renal Cell Carcinoma (RCC), Head and Neck Cancer, Blood Cancer, Glioblastoma, Colorectal Cancer, Pancreatic Cancer, Gastric Cancer, Hepatocellular Carcinoma, Triple-Negative Breast Cancer, Small-Cell Lung Cancer, Bladder Cancer. In Japan, ONO launched it for the treatment of unresectable melanoma in September 2014. Also, ONO is conducting clinical development programs including RCC, NSCLC, Head and Neck Cancer, Gastric Cancer, Esophageal Cancer, Hepatocellular Carcinoma and Hodgkin Lymphoma.

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), the First and Only PD-1 Checkpoint Inhibitor Approved in Europe, for Both First-Line and Previously-Treated Advanced Melanoma Patients

Approval follows accelerated assessment by Committee for Medicinal Products for Human Use, marking a rapid pace in bringing a new option for patients with advanced melanoma

Approval based on CheckMate -066 trial demonstrating superior overall survival vs. dacarbazine in the first-line setting and CheckMate -037 trial showing improved response vs. chemotherapy in previously-treated patients, both at a consistent and well-established dose

Opdivo *safety profile is consistent with previously-reported trials*

(PRINCETON, NJ, June 19, 2015 – Bristol-Myers Squibb Company (NYSE: BMY) today announced that the European Commission has approved *Opdivo*, a PD-1 immune checkpoint inhibitor, for the treatment of advanced (unresectable or metastatic) melanoma in adults, regardless of BRAF status. Today's approval allows for the marketing of *Opdivo* in all 28 Member States of the EU. It follows an accelerated assessment by the Committee for Medicinal Products for Human Use (CHMP), which was announced on April 24, 2015. This accelerated assessment was given because *Opdivo* qualified for the designation as a "medicinal product of major interest from the point of view of public health and in particular from the view point of therapeutic innovation." *Opdivo* is the only PD-1 immune checkpoint inhibitor to receive an accelerated assessment in Europe, and is the first approval given by the European Commission for a PD-1 inhibitor in any cancer.

The incidence of melanoma has continued to increase in almost all European countries, with an estimated one in five patients expected to develop metastatic, or advanced, disease. Historically, prognosis for late-stage metastatic melanoma has been poor: the average survival rate for stage IV is just six months with a one-year mortality rate of 75%.

"At Bristol-Myers Squibb, we are continually focused on developing new ways to transform the outlook for patients with some of the hardest-to-treat and deadliest cancers," said Emmanuel Blin, senior vice president, head of commercialization, policy and operations, Bristol-Myers Squibb. "We are pleased to bring the first PD-1 immune checkpoint inhibitor to the European Union for the treatment of advanced melanoma. We are working relentlessly and at record-breaking speed to build upon our Immuno-Oncology science to deliver new treatment options, with the goal of improving long-term survival for patients."

About CheckMate -066, -037

The European Commission's approval is based on data from two Phase 3 studies (CheckMate -066, -037). Together, the trials investigated *Opdivo* across treatment lines and mutational status with a consistent dose of 3 mg/kg every two weeks that has been well-established across the Phase 3 clinical development program for *Opdivo*.

"The Phase 3 data supporting the approval of *Opdivo* demonstrates both superior overall survival and response rate for treatment-naïve patients with advanced melanoma, against the standard of care," said Dirk Schadendorf, M.D., professor, director and chair, Clinic for Dermatology, University Hospital, Essen, Germany. "It is an important step forward in offering a new option for advanced melanoma patients in the European Union, especially considering that long-term benefits have largely been elusive in this treatment category."

CheckMate -066 is a Phase 3 randomized, double-blind study comparing *Opdivo* (n=210) to the chemotherapy dacarbazine (DTIC) (n=208) in patients with treatment-naïve advanced melanoma. It is the first Phase 3 trial of a PD-1 immune checkpoint inhibitor to demonstrate superior overall survival (OS) in advanced melanoma, demonstrating a one-year survival rate of 73% for *Opdivo* versus 42% for DTIC, and there was a 58% decrease in the risk of death for patients treated with *Opdivo* based on a hazard ratio of 0.42 (99.79% CI, 0.25-0.73; P<0.0001). Objective response rate (ORR) also was significantly higher for *Opdivo* than DTIC (40% vs. 14%, P<0.0001). The primary endpoint of this trial was OS. Secondary endpoints included progression-free survival (PFS) and ORR by RECIST v1.1 criteria.

Safety was reported in all patients treated in the *Opdivo* and DTIC arms. Fewer discontinuations were observed with *Opdivo* than DTIC (6.8% vs. 11.7%) as well as for treatment-related Grade 3/4 adverse events (AEs) (11.7% vs. 17.6%), which were managed using established safety algorithms. The most common *Opdivo* treatment-related AEs were fatigue (20%), pruritus (17%), and nausea (16.5%). Common adverse events in the DTIC arm were consistent with those in previous reports and included nausea (41.5%), vomiting (21%), fatigue (15%), diarrhea (15%) and hematological toxicities. No deaths were attributed to study drug toxicity in either arm.

CheckMate -037 is a Phase 3 randomized, controlled open-label study of *Opdivo* (n=272) versus investigator's choice chemotherapy (ICC) (n=133) -- either single-agent dacarbazine or carboplatin plus paclitaxel -- in patients with advanced melanoma who were previously treated with *Yervoy* (ipilimumab), and, if BRAF mutation positive, a BRAF inhibitor. Co-primary endpoints of the study are ORR and OS. In a planned interim analysis of ORR, an improvement in ORR of 32% was seen in the *Opdivo* arm (95% CI, 23.5%-40.8%) versus 11% in the investigator's choice chemotherapy arm

(95% CI, 3.5%-23.1%). A majority of responses (87%) were ongoing in those patients administered *Opdivo*. Responses to *Opdivo* were demonstrated in both patients with or without BRAF mutuation and regardless of PD-L1 expression.

Safety was reported on all patients treated in the *Opdivo* (n=268) and ICC (n=102) arms. The majority of *Opdivo* treatment-related adverse events (AEs) were Grade 1/2 and managed using recommended treatment algorithms. Grade 3/4 drug-related AEs were less frequent for the *Opdivo* arm (9% vs. 31% of patients treated with chemotherapy). Discontinuations due to drug-related AEs of any grade occurred in 3% of *Opdivo*-treated patients and 7% of patients administered ICC. There were no deaths related to study drug toxicity.

The approval also was based on data from a Phase 1b study (Study -003) in relapsed advanced or metastatic melanoma, which demonstrated the first characterization of *Opdivo* benefit/risk in advanced melanoma. Of the 306 previously-treated patients enrolled in the study, 107 had melanoma and received *Opdivo* at a dose of 0.1 mg/kg, 0.3 mg/kg, 1 mg/kg, 3 mg/kg, or 10 mg/kg every two weeks for a maximum of two years. In this patient population, objective response was reported in 33 patients (31%) with a median duration of response of 22.9 months (95% CI: 17.0, NR). The median PFS was 3.7 months (95% CI: 1.9, 9.3). The median OS was 17.3 months (95% CI: 12.5, 36.7), and the estimated OS rates were 63% (95% CI: 53, 71) at one year, 48% (95% CI: 38, 57) at two years, and 41% (95% CI: 31, 51) at three years.

About *Opdivo*

Bristol-Myers Squibb has a broad, global development program to study *Opdivo* in multiple tumor types consisting of more than 50 trials – as monotherapy or in combination with other therapies – in which more than 8,000 patients have been enrolled worldwide.

Opdivo became the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world on July 4, 2014 when Ono Pharmaceutical Co. announced that it received manufacturing and marketing approval in Japan for the treatment of patients with unresectable melanoma. On December 22, 2014, the U.S. Food and Drug Administration (FDA) granted its first approval for *Opdivo* for the treatment of patients with unresectable or metastatic melanoma and disease progression following *Yervoy* (ipilimumab) and, if BRAF V600 mutation positive, a BRAF inhibitor. On March 4, 2015, *Opdivo* received its second FDA approval for the treatment of patients with metastatic squamous non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy.

IMPORTANT SAFETY INFORMATION

Immune-Mediated Pneumonitis

- Severe pneumonitis or interstitial lung disease, including fatal cases, occurred with OPDIVO treatment. Across the clinical trial experience in 691 patients with solid tumors, fatal immune-mediated pneumonitis occurred in 0.7% (5/691) of patients receiving OPDIVO; no cases occurred in Trial 1 or Trial 3. In Trial 1, pneumonitis, including interstitial lung disease, occurred in 3.4% (9/268) of patients receiving OPDIVO and none of the 102 patients receiving chemotherapy. Immune-mediated pneumonitis occurred in 2.2% (6/268) of patients receiving OPDIVO; one with Grade 3 and five with Grade 2. In Trial 3, immune-mediated pneumonitis occurred in 6% (7/117) of patients receiving OPDIVO, including, five Grade 3 and two Grade 2 cases. Monitor patients for signs and symptoms of pneumonitis. Administer corticosteroids for Grade 2 or greater pneumonitis. Permanently discontinue OPDIVO for Grade 3 or 4 and withhold OPDIVO until resolution for Grade 2.

Immune-Mediated Colitis

- In Trial 1, diarrhea or colitis occurred in 21% (57/268) of patients receiving OPDIVO and 18% (18/102) of patients receiving chemotherapy. Immune-mediated colitis occurred in 2.2% (6/268) of patients receiving OPDIVO; five with Grade 3 and one with Grade 2. In Trial 3, diarrhea occurred in 21% (24/117) of patients receiving OPDIVO. Grade 3 immune-mediated colitis occurred in 0.9% (1/117) of patients. Monitor patients for immune-mediated colitis. Administer corticosteroids for Grade 2 (of more than 5 days duration), 3, or 4 colitis. Withhold OPDIVO for Grade 2 or 3. Permanently discontinue OPDIVO for Grade 4 colitis or recurrent colitis upon restarting OPDIVO.

Immune-Mediated Hepatitis

- In Trial 1, there was an increased incidence of liver test abnormalities in the OPDIVO-treated group as compared to the chemotherapy-treated group, with increases in AST (28% vs 12%), alkaline phosphatase (22% vs 13%), ALT (16% vs 5%), and total bilirubin (9% vs 0). Immune-mediated hepatitis occurred in 1.1% (3/268) of patients receiving OPDIVO; two with Grade 3 and one with Grade 2. In Trial 3, the incidences of increased liver test values were AST (16%), alkaline phosphatase (14%), ALT (12%), and total bilirubin (2.7%). Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater transaminase elevations. Withhold OPDIVO for Grade 2 and permanently discontinue OPDIVO for Grade 3 or 4 immune-mediated hepatitis.

Immune-Mediated Nephritis and Renal Dysfunction

- In Trial 1, there was an increased incidence of elevated creatinine in the OPDIVO-treated group as compared to the chemotherapy-treated group (13% vs 9%). Grade 2 or 3 immune-mediated nephritis or renal dysfunction occurred in 0.7% (2/268) of patients. In Trial 3, the incidence of elevated creatinine was 22%. Immune-mediated renal dysfunction (Grade 2) occurred in 0.9% (1/117) of patients. Monitor patients for elevated serum creatinine prior to and periodically during treatment. For Grade 2 or 3 serum creatinine elevation, withhold OPDIVO and administer corticosteroids; if worsening or no improvement occurs, permanently discontinue OPDIVO. Administer corticosteroids for Grade 4 serum creatinine elevation and permanently discontinue OPDIVO.

Immune-Mediated Hypothyroidism and Hyperthyroidism

- In Trial 1, Grade 1 or 2 hypothyroidism occurred in 8% (21/268) of patients receiving OPDIVO and none of the 102 patients receiving chemotherapy. Grade 1 or 2 hyperthyroidism occurred in 3% (8/268) of patients receiving OPDIVO and 1% (1/102) of patients receiving chemotherapy. In Trial 3, hypothyroidism occurred in 4.3% (5/117) of patients receiving OPDIVO. Hyperthyroidism occurred in 1.7% (2/117) of patients, including one Grade 2 case. Monitor thyroid function prior to and periodically during treatment. Administer hormone replacement therapy for hypothyroidism. Initiate medical management for control of hyperthyroidism.

Other Immune-Mediated Adverse Reactions

- In Trial 1 and 3 (n=385), the following clinically significant immune-mediated adverse reactions occurred in <2% of OPDIVO-treated patients: adrenal insufficiency, uveitis, pancreatitis, facial and abducens nerve paresis, demyeliniation, autoimmune neuropathy, motor dysfunction, and vasculitis. Across clinical trials of OPDIVO administered at doses 3 mg/kg and 10 mg/kg, additional clinically significant, immune-mediated adverse reactions were identified: hypophysitis, diabetic ketoacidosis, hypopituitarism, Guillain-Barré syndrome, and myasthenic syndrome. Based on the severity of adverse reaction, withhold OPDIVO, administer high-dose corticosteroids, and, if appropriate, initiate hormone- replacement therapy.

Embryofetal 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 OPDIVO 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 OPDIVO, advise women to discontinue breastfeeding during treatment.

Serious Adverse Reactions

- In Trial 1, 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 Trial 3, serious adverse reactions occurred in 59% of patients receiving OPDIVO. The most frequent serious adverse drug reactions reported in ≥2% of patients were dyspnea, pneumonia, chronic obstructive pulmonary disease exacerbation, pneumonitis, hypercalcemia, pleural effusion, hemoptysis, and pain.

Common Adverse Reactions

- The most common adverse reactions (≥20%) reported with OPDIVO in Trial 1 were rash (21%) and in Trial 3 were fatigue (50%), dyspnea (38%), musculoskeletal pain (36%), decreased appetite (35%), cough (32%), nausea (29%), and constipation (24%).

Please see U.S. Full Prescribing Information for OPDIVO.

About Advanced Melanoma

Melanoma is a form of skin cancer characterized by the uncontrolled growth of pigment-producing cells (melanocytes) located in the skin. Metastatic melanoma is the deadliest form of the disease, and occurs when cancer spreads beyond the surface of the skin to the other organs, such as the lymph nodes, lungs, brain or other areas of the body. Melanoma is the ninth most common cancer in Europe, with an estimated 100,000 new cases diagnosed annually and more than 20,000 deaths.

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 research in an innovative field of cancer research and treatment known as 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 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, 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 be 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, 2014 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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