September 30, 2015

Opdivo (nivolumab) Demonstrates Long Term Survival Benefit in Patients with Previously Treated Non-Squamous Non-Small Cell Lung Cancer in CheckMate -057

(PRINCETON, NJ, Septemeber 27, 2015) – Bristol-Myers Squibb Company (NYSE:BMY) announced longer term (18 month) survival data from CheckMate -057, an open-label, randomized Phase 3 study evaluating Opdivo (n=292) versus docetaxel (n=290) in previously treated patients with advanced, non-squamous (NSQ) non-small cell lung cancer (NSCLC). Opdivo continued to demonstrate superior overall survival (OS) – the study's primary endpoint – with an estimated 39% of patients alive at 18 months (95% CI, 34-45) versus 23% for docetaxel, based on a minimum follow-up of 17.1 months. Opdivo also continued to demonstrate a reduction in the risk of death by 28% (a hazard ratio of 0.72; 95% CI, 0.60 - 0.88). In the study, Grade 3-4 treatment-related adverse events were reported in 10% of patients treated with Opdivo versus 54% in the docetaxel arm. These data were presented on Monday, September 28 during the 2015 European Cancer Congress (ECC 2015) (Abstract # 3010).

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. In EU, Opdivo was approved for the treatment of advanced (unresectable or metastatic) melanoma in adults regardless of BRAF status in June 2015. European Commission approved Nivolumab BMS for the treatment of locally advanced or metastatic squamous NSCLC after prior chemotherapy in July 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, Urothelial 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, Hodgkin Lymphoma, Urothelial Cancer and Glioblastoma.

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

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Bristol-Myers Squibb

Opdivo (nivolumab) Demonstrates Long Term Survival Benefit in Patients with Previously Treated Non-Squamous Non-Small Cell Lung Cancer in CheckMate -057

***Opdivo* is the first and only PD-1 inhibitor to demonstrate superior overall survival versus docetaxel in non-squamous non-small cell lung cancer, with an 18-month overall survival rate of 39%**

Longer term data from CheckMate -057 show benefit with* Opdivo *in overall population with greater magnitude of survival benefit among PD-L1 expressors

Safety and tolerability profile of* Opdivo *is favorable versus docetaxel and consistent with prior* Opdivo *studies

Results from CheckMate -057 published in the New England Journal of Medicine

(PRINCETON, NJ, Septemeber 27, 2015) – Bristol-Myers Squibb Company (NYSE:BMY) today announced longer term (18 month) survival data from CheckMate -057, an open-label, randomized Phase 3 study evaluating *Opdivo* (n=292) versus docetaxel (n=290) in previously treated patients with advanced, non-squamous (NSQ) non-small cell lung cancer (NSCLC). *Opdivo* continued to demonstrate superior overall survival (OS) – the study's primary endpoint – with an estimated 39% of patients alive at 18 months (95% CI, 34-45) versus 23% for docetaxel, based on a minimum follow-up of 17.1 months. *Opdivo* also continued to demonstrate a reduction in the risk of death by 28% (a hazard ratio of 0.72; 95% CI, 0.60 - 0.88). In the study, Grade 3-4 treatment-related adverse events were reported in 10% of patients treated with *Opdivo* versus 54% in the docetaxel arm. These data will be presented on Monday, September 28 during the 2015 European Cancer Congress (ECC 2015) (Abstract # 3010) and published in the *New England Journal of Medicine*.

"These longer term survival results for nivolumab in advanced, non-squamous non-small cell lung cancer support the potential for this Immuno-Oncology agent in treating lung cancer patients," said Leora Horn, M.D., Vanderbilt-Ingram Cancer Center. "CheckMate -057 builds upon its critical findings and now, data show a sustained survival benefit for nivolumab in this hard-to-treat disease that is incredibly encouraging for oncologists, and most importantly, for our patients."

CheckMate -057 clinical results were first reported at the 51st Annual Meeting of the American Society of Clinical Oncology, marking the first time a PD-1 inhibitor demonstrated superior OS versus docetaxel in previously treated patients with NSQ NSCLC. Data from this trial have been accepted for regulatory review by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency to expand the respective *Opdivo* indications to include previously treated patients with NSQ

NSCLC. This application has also been granted Priority Review in the U.S., and *Opdivo* has received Breakthrough Therapy Designation for this indication.

"At the core of our Immuno-Oncology approach is an unrelenting focus to fundamentally change survival expectations for all cancer patients. Today, we are driving insights into how advanced lung cancer may be treated – from defining the role of PD-L1 expression to showing clinical efficacy resulting in deep and durable responses for these patients," said Michael Giordano, senior vice president, head of Development, Oncology. "The 18-month data from CheckMate -057 reinforce the potential for *Opdivo*, across PD-L1 expression levels, to offer patients durable overall survival benefit with lower incidence of serious adverse events versus chemotheraphy."

About CheckMate -057

CheckMate -057 is a Phase 3, open-label, randomized clinical trial that evaluated patients with advanced NSQ NSCLC who had progressed during or after one prior platinum doublet-based chemotherapy regimen. The trial included patients regardless of their PD-L1 status. Secondary endpoints included objective response rate (ORR) and progression-free survival (PFS). Patients enrolled in the trial received *Opdivo* 3 mg/kg every two weeks versus standard of care, docetaxel, at 75 mg/m^2 every three weeks. In the trial, *Opdivo* demonstrated continued superior OS benefit, with an estimated 51% of patients alive at one year versus 39% for docetaxel, and an estimated 39% of patients alive at 18 months (95% CI, 34-45) versus 23% for docetaxel, based on a minimum follow-up of 17.1 months.

CheckMate -057 also evaluated the efficacy of *Opdivo* by tumor PD-L1 expression. Of randomized patients, 78% (455/582) had tumor samples evaluable for PD-L1 expression. Rates of PD-L1 expressing tumors were balanced between groups. PD-L1 status was predictive for benefit from *Opdivo,* across pre-specified 1%, 5%, and 10% expression levels. In PD-L1 non-expressors, OS was similar between *Opdivo* and docetaxel, with improved durability of responses seen in patients treated with *Opdivo* versus docetaxel.

In addition, clinical results showed confirmed ORR was significantly higher for *Opdivo* (19%) than docetaxel (12%). For patients administered *Opdivo*, median duration of response was 17.2 months and 5.6 months for docetaxel. One-year PFS was 19% for *Opdivo* (95% CI, 14-23) and 8% for docetaxel (95% CI, 5-12). Median PFS was 2.3 months for *Opdivo* (95% CI, 2.2-3.3) and 4.2 months for docetaxel (95% CI, 3.5-4.9).

The safety profile of *Opdivo* in CheckMate -057 was consistent with prior studies and similar across expressors and non-expressors. Treatment-related adverse events were low in severity with *Opdivo* and occurred less frequently (any grade: 69%; grade 3-4: 10%) than docetaxel (any grade:

88%; grade 3-4: 54%), including both hematologic and non-hematologic toxicities. Treatment-related serious adverse events were reported less frequently with *Opdivo* (any grade: 7%; grade 3-4: 5%) than docetaxel (any grade: 20%; grade 3-4: 18%). Discontinuation due to treatment–related adverse events was less frequent with *Opdivo* (5%) than docetaxel (15%).

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. Lung cancer results in more deaths worldwide than colorectal, breast and prostate cancers combined. Non-small cell lung cancer is one of the most common types of the disease and accounts for approximately 85% of cases.

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 a monotherapy or in combination with other therapies – in which more than 8,000 patients have been enrolled worldwide.

Opdivo is a programmed death-1 (PD-1) immune checkpoint inhibitor that has received approval from the FDA as a monotherapy in two cancer indications. *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. In the U.S., the 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. This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. On March 4, 2015, *Opdivo* received its second FDA approval for the treatment of patients with metastatic squamous (SQ) non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. On July 20, 2015 the European Commission approved Nivolumab BMS for the treatment of locally advanced or metastatic SQ NSCLC after prior chemotherapy.

INDICATION

OPDIVO® (nivolumab) is indicated 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.

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 Co., Bristol-Myers Squibb expanded its territorial rights to develop and commercialize *Opdivo* globally except in Japan, South Korea and Taiwan, where Ono had retained all rights to the compound at the time. On July 23, 2014, Bristol-Myers Squibb and Ono Pharmaceutical further expanded the companies' strategic collaboration agreement to jointly develop and commercialize multiple immunotherapies – as single agents and combination regimens – for patients with cancer in Japan, South Korea and Taiwan.

About Bristol-Myers Squibb

Bristol-Myers Squibb is a global 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 www.bms.com, or follow us on Twitter at http://twitter.com/bmsnews.

Bristol-Myers Squibb Forward-Looking Statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that Opdivo will receive regulatory approval for an additional indication in lung cancer. 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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