September 11, 2015

Follow-up Data from Two Pivotal Opdivo (nivolumab) Trials

Demonstrates Sustained Survival Results

in Patients with Previously Treated Squamous Non-Small Cell Lung Cancer

(PRINCETON, NJ, September 7, 2015) – Bristol-Myers Squibb Company (NYSE: BMY) announced longer term survival and safety data from CheckMate -017 and -063, two pivotal trials evaluating Opdivo in previously treated squamous (SQ) non-small cell lung cancer (NSCLC), showing sustained survival benefit across these studies. In both trials, Opdivo showed an estimated 18 month overall survival (OS) rate of 27% (CheckMate -063) to 28% (CheckMate -017); survival benefit was independent of PD-L1 expression. The safety profile of Opdivo is consistent with previously-reported trials, and in CheckMate -017, is also favorable compared to docetaxel. These data was presented at the 16th World Conference on Lung Cancer (Abstract #736, CheckMate -017 and #828, CheckMate -063).

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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Follow-up Data from Two Pivotal *Opdivo* (nivolumab) Trials Demonstrates Sustained Survival Results in Patients with Previously Treated Squamous Non-Small Cell Lung Cancer

***Opdivo* is the only PD-1 immune checkpoint inhibitor to show a sustained survival benefit in this patient population, as demonstrated in both CheckMate -017 and -063**

Clinical benefit observed among both PD-L1 expressors and non-expressors, across both trials

Safety and tolerability profile at 18 month follow-up is consistent with previously-reported results from these trials

(PRINCETON, NJ, September 7, 2015) – Bristol-Myers Squibb Company (NYSE: BMY) today announced longer term survival and safety data from CheckMate -017 and -063, two pivotal trials evaluating *Opdivo* in previously treated squamous (SQ) non-small cell lung cancer (NSCLC), showing sustained survival benefit across these studies. In both trials, *Opdivo* showed an estimated 18 month overall survival (OS) rate of 27% (CheckMate -063) to 28% (CheckMate -017); survival benefit was independent of PD-L1 expression. The safety profile of *Opdivo* is consistent with previously-reported trials, and in CheckMate -017, is also favorable compared to docetaxel. These data will be presented today at the 16th World Conference on Lung Cancer (Abstract #736, CheckMate -017 and #828, CheckMate -063).

"Immuno-Oncology agents like *Opdivo* provide a novel approach to treating cancer. The improvement in survival observed in advanced squamous non-small cell lung cancer represents an important step forward for our patients," said Suresh S. Ramalingam, M.D., director, Division of Medical Oncology, Winship Cancer Institute of Emory University. "These updated results demonstrate the ability to achieve longer term survival outcomes in this patient population. In fact, the Kaplan-Meier curve from this study suggests a prolonged survival benefit for a subset of patients."

Previously-reported one year results from CheckMate -017 showed a significantly superior OS rate of 42% versus 24% for docetaxel. In CheckMate -063, the estimated one-year survival rate was 39%. (see table below)

	CheckMate -017		CheckMate -063
	Nivolumab N = 135	Docetaxel N = 137	Nivolumab N = 117
1-Year Overall Survival	42%	24%	39%
18-Month Overall Survival	28%	13%	27%

"Our approach to Immuno-Oncology research is intended to show meaningful improvement over the traditional standard of care on the benchmark endpoint of overall survival," said Michael Giordano, senior vice president, head of Development, Oncology. "We have taken a comprehensive research approach in lung cancer, one focused on a commitment to providing the first major advancement in squamous non-small cell lung cancer in more than a decade – *Opdivo* – that offers the potential to replace chemotherapy. With the data presented today, we remain confident in our Immuno-Oncology strategy, including fulfilling our goal in showing the survival benefit for *Opdivo*, not only in non-small cell lung cancer, but similar to the data already observed in advanced melanoma and other tumor types."

About CheckMate -017 & CheckMate -063

CheckMate -017 and CheckMate -063 demonstrated the efficacy and safety of *Opdivo* in patients with advanced or metastatic SQ NSCLC who had progressed following previous chemotherapy treatment. Together, the trials investigated *Opdivo* monotherapy at a dose of 3 mg/kg every two weeks, which has been well-established across the Phase 3 *Opdivo* clinical development programs for various tumors. These trials also formed the basis for *Opdivo*'s approvals in the U.S. and European Union, and helped to establish the agent as standard of care for previously treated SQ NSCLC.

CheckMate -017 is a landmark Phase 3, open-label, randomized clinical trial that evaluated *Opdivo* (n=135) 3mg/kg intravenously over 60 minutes every two weeks versus standard of care, docetaxel (n=137) 75 mg/m^2 intravenously administered every three weeks in patients with advanced SQ NSCLC who had progressed during or after one prior platinum doublet-based chemotherapy regimen. The study's primary endpoint was OS and secondary endpoints included progression-free survival (PFS) and objective response rate (ORR). The trial included patients regardless of their PD-L1 expression status.

CheckMate -017 showed a doubling in 18 month OS benefit with an estimated 28% of patients alive at 18 months for *Opdivo* versus 13% for docetaxel. The median OS for the *Opdivo* arm was 9.2 months and 6.0 months for docetaxel (hazard ratio: 0.62 [95% CI, 0.48, 0.81; P = 0.0004]). In addition, *Opdivo* showed a statistically significant improvement in PFS and ORR. The PFS rate at18 months was

17% for the *Opdivo* arm versus 2.7% for docetaxel. Median PFS was 3.5 months for patients administered *Opdivo* versus 2.8 months for docetaxel (hazard ratio: 0.63; [95% CI, 0.48, 0.83; P = 0.0008]). The ORR was 20% for the *Opdivo* arm versus 9% for docetaxel for an estimated odds ratio of 2.6 (95% CI, 1.3, 5.5; P = 0.0083), with an ongoing response seen in 63% of patients treated with *Opdivo*. In the trial, 28 patients were treated with *Opdivo* beyond initial progression, and nine demonstrated a non-conventional pattern of benefit (7%). The safety profile of *Opdivo* continued to be favorable versus docetaxel and treatment-related AEs occurred less frequently with *Opdivo* (n=131; any grade, 59%; grade 3–5, 8%; no grade 5 events) than docetaxel (n=129; any grade, 87%; grade 3–5, 58%), including both hematologic and non-hematologic toxicities. The majority of treatment-related select AEs in patients receiving *Opdivo* occurred within the first three months of treatment.

CheckMate -063 is a Phase 2, single-arm, open-label trial that included patients with metastatic SQ NSCLC who had progressed after receiving a platinum-based therapy and at least one additional systemic treatment regimen (n=117). In this trial, *Opdivo* showed an estimated 18-month OS rate of 27%. At 18 months, confirmed objective response rate, the study's primary endpoint, was 15% (95% CI: 9, 22). Median OS was 8.1 months (95% CI: 6.1, 10.9). Most treatment-related AEs were of low grade (any grade, 75%; grade 3-4, 17%) and managed using established treatment algorithms.

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 (NSCLC) is one of the most common types of the disease and accounts for approximately 85% of cases. Squamous cell NSCLC accounts for approximately 25% to 30% of all lung cancer cases. Five year survival rates vary globally depending on the stage and type of lung cancer.

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. 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, 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 at www.bms.com.

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. 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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