June 2, 2015

Opdivo (nivolumab) Demonstrates Superior Survival Compared to Standard of Care (docetaxel) for Previously-Treated Squamous Non-Small Cell Lung Cancer in Phase III Trial

(PRINCETON, NJ, May 31, 2015) – Bristol-Myers Squibb Company (NYSE: BMY) announced results from CheckMate -017, a Phase III, open-label, randomized study evaluating Opdivo (n=135) versus docetaxel (n=137) in previously treated patients with advanced, squamous non-small cell lung cancer. At one year, Opdivo demonstrated an overall survival rate of 42% versus 24% for docetaxel, with a median overall survival of 9.2 months versus 6 months, respectively. In the trial, Opdivo reduced the risk of death by 41%, based upon a hazard ratio of 0.59 (95% CI, 0.44-0.79; P = 0.00025). The safety profile of Opdivo in CheckMate -017 was consistent with prior studies and favorable versus docetaxel.

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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Bristol-Myers Squibb

Opdivo (nivolumab) Demonstrates Superior Survival Compared to Standard of Care (docetaxel) for Previously-Treated Squamous Non-Small Cell Lung Cancer in Phase III Trial

- *Opdivo is the first major treatment advance in more than a decade showing a survival benefit in squamous non-small cell lung cancer*
- *In CheckMate -017, Opdivo (nivolumab) showed a superior one year overall survival rate of 42% vs. 24% for docetaxel*
- *Opdivo demonstrated significant superiority across all endpoints including response rate and progression-free survival versus standard of care in PD-L1 expressers and non-expressers*
- *Findings presented today at annual meeting of the American Society of Clinical Oncology and silmultaneouly published in the New England Journal of Medicine*

(PRINCETON, NJ, May 31, 2015) – Bristol-Myers Squibb Company (NYSE: BMY) today announced results from CheckMate -017, a Phase III, open-label, randomized study evaluating *Opdivo* (n=135) versus docetaxel (n=137) in previously treated patients with advanced, squamous non-small cell lung cancer. At one year, *Opdivo* demonstrated an overall survival rate of 42% versus 24% for docetaxel, with a median overall survival of 9.2 months versus 6 months, respectively. In the trial, *Opdivo* reduced the risk of death by 41%, based upon a hazard ratio of 0.59 (95% CI, 0.44-0.79; P = 0.00025). The safety profile of *Opdivo* in CheckMate -017 was consistent with prior studies and favorable versus docetaxel. Findings from CheckMate -017 were published today in *The New England Journal of Medicine* and presented during an oral abstract session at the 51st Annual Meeting of the American Society of Clinical Oncology (Abstract #8009).

"Historically, treatment options for lung cancer patients have been limited. The *Opdivo* data presented today offer patients the first major advance in the treatment of squamous non-small cell lung cancer in more than a decade," said David Spigel, MD, Sarah Cannon Research Institute. "In this study *Opdivo* not only demonstrated superior overall survival and objective response rate versus chemotherapy, the standard of care, but these benefits were sustained over time. The study also showed that squamous non-small cell lung cancer has a unique biology that resulted in similar efficacy across levels of PD-L1 expression."

Opdivo demonstrated a consistent statistically significant superiority over docetaxel across all secondary endpoints including overall response rate and progression-free survival. Results showed that,

at one year, *Opdivo* improved progression-free survival (21%) versus docetaxel (6.4%). Median progression-free survival was 3.5 months for *Opdivo* and 2.8 months for docetaxel, with a hazard ratio of 0.62 (95% CI, 0.47-0.81; P = 0.0004). *Opdivo* also produced a significantly higher confirmed objective response rate (20%) versus docetaxel (8.8%) (95% CI; P=0.0083). Responses for *Opdivo* were ongoing and the median duration of response was not reached (range 2.9 to 21+ months) with at least 11 months of follow-up; the median duration of response for docetaxel was 8.4 months (range 1.4+ to 15+ months).

"The results from CheckMate -017 are an important milestone in cancer research. This study marked the first time a PD-1 immune checkpoint inhibitor demonstrated a survival benefit in lung cancer, thereby establishing a new treatment modality for the disease," said Michael Giordano, senior vice president, Head of Development, Oncology. "The results announced today also build on and confirm our clinical research approach to understanding the role of PD-L1 expression and degree of benefit for *Opdivo* across histologies and etiologies in non-small cell lung cancer. This is incredibly encouraging news as we continue to study potential new options that may improve upon, and potentially replace, the current standard of care."

About CheckMate -017

CheckMate -017 was a Phase III, open-label, randomized clinical trial that evaluated *Opdivo* 3 mg/kg intravenously over 60 minutes every two weeks versus standard of care, docetaxel 75 mg/m2 intravenously administered every 3 weeks in patients with advanced squamous non-small cell lung cancer who had progressed during or after one prior platinum doublet-based chemotherapy regimen. The study's primary endpoint was overall survival and secondary endpoints included progression-free survival and response rate. The trial included patients regardless of their PD-L1 (programmed death ligand-1) expression status.

Of randomized patients in the trial (n=272), 83% (225) had quantifiable PD-L1 expression. Rates of PD-L1 positivity were balanced between treatment groups. Across pre-specified expression levels (1%, 5%, and 10%), *Opdivo* demonstrated superior benefit across all endpoints independent of PD-L1 expression. Overall and progression-free survival among PD-L1 subgroups favored *Opdivo* and was similar to the primary population. Similar objective response rates were observed in patients with high and low, or no PD-L1 expression, and were consistently higher for *Opdivo* versus docetaxel.

The safety profile of *Opdivo* in CheckMate -017 was consistent with prior studies and favorable versus docetaxel. Treatment-related adverse events occurred less frequently with *Opdivo* (any grade,

58%; grade 3–4, 6.9%; no grade 5 events) than docetaxel (any grade, 86%; grade 3–4, 55%; grade 5, 2.3%), including both hematologic and non-hematologic toxicities.

About Non-Small Cell 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 percent of cases. Survival rates vary depending on the stage and type of the cancer when it is diagnosed. Globally, the five-year survival rate for Stage I non-small cell lung cancer is between 47 and 50 percent; for Stage IV non-small cell lung cancer, the five-year survival rate drops to two percent.

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. In the U.S., 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 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 3. 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 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 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 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 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.

Immune-Mediated Adverse Reactions

- 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 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 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 available 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 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 receive regulatory approval for an additional indication in lung cancer or, if approved, that it will become commercially successful. 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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