June 3, 2015

Opdivo (nivolumab) First PD-1 Inhibitor to Demonstrate Superior Overall Survival Versus Standard of Care (docetaxel) in Previously-Treated Non-Squamous Non-Small Cell Lung Cancer in Pivotal Phase III Trial

(PRINCETON, NJ, May 29, 2015) – Bristol-Myers Squibb Company (NYSE: BMY) announced that Opdivo (nivolumab) is the first PD-1 inhibitor to demonstrate superior overall survival versus standard of care (docetaxel) in an open-label, randomized Phase III study (CheckMate -057) evaluating previously-treated patients with advanced, non-squamous non-small cell lung cancer (NSCLC). A 27% reduction in the risk of progression or death – the primary study endpoint – was reported for Opdivo (n=292) versus docetaxel (n=290) based upon a hazard ratio of 0.73 (96% CI, 0.59-0.89; P = 0.0015). Opdivo was associated with a doubling of overall median survival across the continuum of PD-L1 expression, starting at 1% level of expression, in the trial. The safety profile of Opdivo in CheckMate -057 was favorable versus docetaxel with grade 3–5 treatment-related adverse events reported in 10% of patients who were treated with Opdivo versus 54% in the docetaxel arm.

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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Opdivo (nivolumab) First PD-1 Inhibitor to Demonstrate Superior Overall Survival Versus Standard of Care (docetaxel) in Previously-Treated Non-Squamous Non-Small Cell Lung Cancer in Pivotal Phase III Trial

- *CheckMate -057 demonstrates clear role for PD-L1 expression in non-squamous NSCLC; PD-L1 expressers (>1%) associated with doubling of median overall survival (17 to 19 months) compared with standard of care (8 to 9 months)*
- *Opdivo demonstrated similar efficacy and favorable tolerability profile versus standard of care in PD-L1 non-expressers*
- *Opdivo decreased risk of progression or death by 27% compared to standard of care*
- *Safety and tolerability profile of Opdivo is consistent with prior studies and favorable versus current standard of care*
- *Marks second positive Phase III trial for Opdivo in previously-treated NSCLC*

(PRINCETON, NJ, May 29, 2015) – Bristol-Myers Squibb Company (NYSE: BMY) today announced that *Opdivo* (nivolumab) is the first PD-1 inhibitor to demonstrate superior overall survival versus standard of care (docetaxel) in an open-label, randomized Phase III study (CheckMate -057) evaluating previously-treated patients with advanced, non-squamous non-small cell lung cancer (NSCLC). A 27% reduction in the risk of progression or death – the primary study endpoint – was reported for *Opdivo* (n=292) versus docetaxel (n=290) based upon a hazard ratio of 0.73 (96% CI, 0.59-0.89; P = 0.0015). *Opdivo* was associated with a doubling of overall median survival across the continuum of PD-L1 expression, starting at 1% level of expression, in the trial. The safety profile of *Opdivo* in CheckMate -057 was favorable versus docetaxel with grade 3–5 treatment-related adverse events reported in 10% of patients who were treated with *Opdivo* versus 54% in the docetaxel arm.

These data will be featured today, May 29, during the 51st Annual Meeting of the American Society of Clinical Oncology (ASCO) press briefing at 1:00 – 2:00 PM CDT and presented during a clinical science symposium on Saturday, May 30 from 8:51 – 9:03 AM CDT (Late Breaking Abstract #109).

"CheckMate -057 results reported today mark a milestone in the development of new treatment options for lung cancer, as *Opdivo* is the first PD-1 inhibitor to show a significant improvement in overall survival in a Phase III trial in non-squamous non-small cell lung cancer compared with the current standard of care, docetaxel," said Luis Paz-Ares, MD, Hospital Universitario Doce de Octubre,

Madrid, Spain. “Our goal with clinical cancer research is to always look for new options that may improve upon, or in some cases replace, current standard of care. The CheckMate -057 results represent progress toward establishing a new standard of care that may replace docetaxel in PD-L1 expressers.”

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. Survival rates vary depending on the stage and type of the cancer when it is diagnosed.

“The survival results from this Phase III trial, as well as from CheckMate -017 in squamous NSCLC, validate the Bristol-Myers Squibb development strategy for *Opdivo* to improve survival expectations for patients with lung cancer,” said Michael Giordano, senior vice president, Head of Development, Oncology, Bristol-Myers Squibb. “The CheckMate -057 results defined the role for PD-L1 expression, based upon an overall survival endpoint and showed that patients whose tumor expressed PD-L1 at 1% or greater levels achieved a doubling of overall survival. This represents a significant scientific advance in non-small cell lung cancer.”

About CheckMate -057

CheckMate -057 is a landmark Phase III, open-label, randomized clinical trial that evaluated patients with advanced non-squamous 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, progression-free survival and efficacy by tumor PD-L1 expression. Patients enrolled in the trial were administered *Opdivo* 3 mg/kg every two weeks versus standard of care, docetaxel, at 75 mg/m2 every three weeks.

In addition to improving overall survival, *Opdivo* demonstrated a superior objective response rate of 19% versus 12% for docetaxel (P = 0.0246). The median duration of response for *Opdivo* was 17.2 months versus 5.6 months for docetaxel, and median time to response of 2.1 months vs. 2.6 months, respectively.

CheckMate -057 also evaluated the efficacy of *Opdivo* by tumor PD-L1 expression. Of randomized patients, 78% (455/582) had tumor samples allowing the assessment of PD-L1 expression. Rates of PD-L1 expressing tumors were balanced between groups. Across pre-specified 1%, 5%, and 10% expression levels, PD-L1 status was predictive for benefit from *Opdivo*. In patients with PD-L1 expressing tumors, *Opdivo* demonstrated improved efficacy across all endpoints at all expression levels (chart below).

Efficacy Summary: Median Overall Survival by PD-L1 Expression

	Opdivo	Docetaxel
≥1% PD-L1 expression level HR = 0.59 (95% CI, 0.43- 0.82)	17.2 months	9.0 months
<1% PD-L1 expression level HR = 0.90 (95% CI, 0.66- 1.24)	10.4 months	10.1 months
≥5% PD-L1 expression level HR = 0.43 (95% CI, 0.30-0.63)	18.2 months	8.1 months
<5% PD-L1 expression level HR = 1.01 (95% CI, 0.77- 1.34)	9.7 months	10.1 months
≥10% PD-L1 expression level HR = 0.40 (95% CI, 0.26-0.59)	19.4 months	8.0 months
<10% PD-L1 expression level HR = 1.00 (95% CI, 0.76- 1.31)	9.9 months	10.3 months

The safety profile of *Opdivo* in CheckMate -057 was consistent with prior studies and favorable versus docetaxel. Safety profile also was similar across expressers and non-expressers. 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: 7.3%; grade 3–4: 5.2%) 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%).

Proven Efficacy Across Histologies in Lung Cancer

CheckMate -057 is the second positive Phase III trial to demonstrate superior overall survival for *Opdivo* in non-small cell lung cancer. Earlier this year, the Phase III CheckMate -017 trial was stopped early due to superior overall survival versus docetaxel in previously-treated advanced squamous non-small cell lung cancer and formed the basis of the company's first indication in lung cancer from the U.S. Food & Drug Administration's (FDA) approval for *Opdivo*. Trial results from CheckMate -017 will be presented at ASCO during an oral abstract session on Sunday, May 31 from 4:30 – 4:42 PM CDT (Abstract #8009).

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 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 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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