Bristol-Myers Squibb and Incyte to Advance the Combination of Opdivo (nivolumab) and Epacadostat into First-line Registrational Trials

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- Companies to initiate Phase 3 registrational trials in first-line non-small cell lung cancer across the spectrum of PD-L1 expression and first-line head and neck cancer in 2017
- Collaboration will add additional I-O relapsed/refractory melanoma cohorts to ECHO-204, the ongoing Phase 1/2 multi-tumor study of epacadostat plus Opdivo

NEW YORK & WILMINGTON, Del.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) and Incyte Corporation (Nasdaq:INCY) today announced the companies have agreed to advance their clinical development program evaluating the combination of epacadostat, Incyte's investigational oral selective IDO1 enzyme inhibitor, with Opdivo (nivolumab), Bristol-Myers Squibb's PD-1 immune checkpoint inhibitor, into phase 3 registrational studies in first-line non-small cell lung cancer across the spectrum of PD-L1 expression and first-line head and neck cancer. Additionally, the companies are expanding the ECHO-204 Phase 1/2 study, established under a collaboration between the companies in 2014, to include anti-PD-1/PD-L1 relapsed/refractory melanoma cohorts. The expanded clinical development program, including the phase 3 registrational studies, will be co-funded by the two companies.

“We are pleased to build upon our existing collaboration with Incyte and advance the clinical development of epacadostat combined with Opdivo into phase 3 registrational trials,” said Fouad Namouni, M.D., head of Development, Oncology, Bristol-Myers Squibb. “Incyte shares our goal of improving clinical outcomes for patients with some of the hardest-to-treat cancers, and we look forward to working together on studies evaluating the clinical outcomes of this therapeutic combination.”

“We are very pleased to expand our partnership with Bristol-Myers Squibb and move the combination of epacadostat plus Opdivo forward into pivotal studies,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “We believe that further expanding the ECHO development program for epacadostat, including the initiation of these new Phase 3 trials, will bring us closer to our goal of providing new treatment options for patients with certain cancers.”

About Epacadostat (INCB024360)
Indoleamine 2,3-dioxygenase 1 (IDO1) is a key immunosuppressive enzyme that modulates the anti-tumor immune response by promoting regulatory T cell generation and blocking effector T cell activation, thereby facilitating tumor growth by allowing cancer cells to avoid immune surveillance. Epacadostat is a first-in-class, highly potent and selective oral inhibitor of the IDO1 enzyme that is designed to reverse tumor-associated immune suppression and restore effective anti-tumor immune responses. In single-arm studies, the combination of epacadostat and immune checkpoint inhibitors has shown proof-of-concept in patients with unresectable or metastatic melanoma.

About the Opdivo Clinical Development Program
Bristol-Myers Squibb’s global development program founded on scientific expertise in the field of Immuno-Oncology includes a broad range of clinical trials studying Opdivo, across all phases, including Phase 3, in a variety of tumor types. To date, the Opdivo clinical development program has enrolled more than 25,000 patients.

About Opdivo
Opdivo is a programmed death-1 (PD-1) immune checkpoint inhibitor that is designed to uniquely harness the body's own immune system to help restore anti-tumor immune response. By harnessing the body’s own immune system to fight cancer, Opdivo has become an important treatment option across multiple cancers.

Opdivo’s leading global development program is based on Bristol-Myers Squibb’s scientific expertise in the field of Immuno-Oncology and includes a broad range of clinical trials across all phases, including Phase 3, in a variety of tumor types. To date, the Opdivo clinical development program has enrolled more than 25,000 patients. The Opdivo trials have contributed to gaining a deeper understanding of the potential role of biomarkers in patient care, particularly regarding how patients may
benefit from Opdivo across the continuum of PD-L1 expression.

In July 2014, Opdivo was the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world. Opdivo is currently approved in more than 57 countries, including the United States, the European Union and Japan. In October 2015, the company’s Opdivo and Yervoy combination regimen was the first Immuno-Oncology combination to receive regulatory approval for the treatment of metastatic melanoma and is currently approved in more than 47 countries, including the United States and the European Union.

OPDIVO AND YERVOY INDICATIONS & IMPORTANT SAFETY INFORMATION

INDICATIONS
OPDIVO® (nivolumab) as a single agent is indicated for the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

OPDIVO® (nivolumab) as a single agent is indicated for the treatment of patients with BRAF V600 wild-type unresectable or metastatic melanoma.

OPDIVO® (nivolumab), in combination with YERVOY® (ipilimumab), is indicated for the treatment of patients with unresectable or metastatic melanoma. This indication is approved under accelerated approval based on progression-free survival. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

OPDIVO® (nivolumab) is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO.

OPDIVO® (nivolumab) is indicated for the treatment of patients with advanced renal cell carcinoma (RCC) who have received prior anti-angiogenic therapy.

OPDIVO® (nivolumab) is indicated for the treatment of patients with classical Hodgkin lymphoma (cHL) that has relapsed or progressed after autologous hematopoietic stem cell transplantation (HSCT) and post-transplantation brentuximab vedotin. This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

OPDIVO® (nivolumab) is indicated for the treatment of patients with recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) with disease progression on or after platinum-based therapy.

OPDIVO® (nivolumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION

WARNING: IMMUNE-MEDIATED ADVERSE REACTIONS

YERVOY can result in severe and fatal immune-mediated adverse reactions. These immune-mediated reactions may involve any organ system; however, the most common severe immune-mediated adverse reactions are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of YERVOY.

Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrinopathy and evaluate clinical chemistries including liver function tests (LFTs), adrenocorticotropic hormone (ACTH) level, and thyroid function tests at baseline and before each dose.

Permanently discontinue YERVOY and initiate systemic high-dose corticosteroid therapy for severe immune-mediated reactions.

Immune-Mediated Pneumonitis

OPDIVO can cause immune-mediated pneumonitis. Fatal cases have been reported. Monitor patients for signs with radiographic imaging and for symptoms of pneumonitis. Administer corticosteroids for Grade 2 or more severe pneumonitis. Permanently discontinue for Grade 3 or 4 and withhold until resolution for Grade 2. In patients receiving OPDIVO monotherapy, fatal cases of immune-mediated pneumonitis have occurred. Immune-mediated pneumonitis occurred in 3.1% (61/1994) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated pneumonitis occurred in 6% (25/407) of patients.

In Checkmate 205 and 039, pneumonitis, including interstitial lung disease, occurred in 4.9% (13/263) of patients receiving OPDIVO. Immune-mediated pneumonitis occurred in 3.4% (9/263) of patients receiving OPDIVO: Grade 3 (n=1) and Grade 2 (n=8).

Immune-Mediated Colitis

OPDIVO can cause immune-mediated colitis. Monitor patients for signs and symptoms of colitis. Administer corticosteroids...
OPDIVO can cause immune-mediated encephalitis. Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater transaminase elevations. Withhold for Grade 2 and permanently discontinue for Grade 4. In patients receiving OPDIVO monotherapy, immune-mediated encephalitis occurred in 2.9% (58/1994) of patients in studies with YERVOY. Across all YERVOY-treated patients in that study (n=511), 5 (1%) developed intestinal perforation, 4 (0.8%) died as a result of complications, and 26 (5%) were hospitalized for severe enterocolitis.

**Immune-Mediated Nephritis and Renal Dysfunction**

OPDIVO can cause immune-mediated nephritis. Monitor patients for signs and symptoms of nephritis, including proteinuria, hematuria, hypertension, and decreased creatinine clearance. Withhold for Grade 2 and permanently discontinue for Grade 4. In patients receiving OPDIVO monotherapy, immune-mediated nephritis occurred in 1.2% (23/1994) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated nephritis and renal dysfunction occurred in 2.2% (9/407) of patients.

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal hepatotoxicity (AST or ALT elevations >5x the ULN or total bilirubin elevations >3x the ULN; Grade 3-5) occurred in 8 (2%) patients, with fatal hepatic failure in 0.2% and hospitalization in 0.4%.

**Immune-Mediated Endocrinopathies**

OPDIVO can cause immune-mediated hypophysitis, adrenal insufficiency, autoimmune thyroid disorders, Type 1 diabetes mellitus. Monitor patients for signs and symptoms of hypophysitis, including hypothyroidism, adrenal insufficiency, and signs of adrenal insufficiency, thyroid function prior to and periodically during treatment, and hyperglycemia. Administer hormone replacement as clinically indicated and corticosteroids for Grade 2 or greater hypophysitis. Withhold for Grade 2 and permanently discontinue for Grade 4 hypophysitis. In patients receiving OPDIVO monotherapy, immune-mediated hypophysitis occurred in 1.8% (35/1994) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated hypophysitis occurred in 13% (51/407) of patients.

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal hepatotoxicity (AST or ALT elevations >5x the ULN or total bilirubin elevations >3x the ULN; Grade 3-5) occurred in 8 (2%) patients, with fatal hepatic failure in 0.2% and hospitalization in 0.4%.

**Immune-Mediated Neuropathies**

In a separate Phase 3 study of YERVOY 3 mg/kg, 1 case of fatal Guillain-Barré syndrome and 1 case of severe (Grade 3) peripheral motor neuropathy were reported.

**Immune-Mediated Dermatitis**

OPDIVO can cause immune-mediated rash, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), some cases with fatal outcome. Monitor patients for signs of SJS or TEN. Withhold OPDIVO and refer the patient for specialized care for assessment and treatment. If confirmed, permanently discontinue. In patients receiving OPDIVO monotherapy, immune-mediated rash occurred in 9% (36/407) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated dermatitis (including SJS and TEN) occurred in 2.5% (12/494) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated rash and dermatitis occurred in 2.5% (12/494) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated rash and dermatitis occurred in 2.5% (12/494) of patients.

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal immune-mediated dermatitis occurred in 0.9% (17/1994) of patients. In patients receiving OPDIVO with YERVOY, hypersensitivity syndrome occurred in 0.5% (6/1207) of patients.

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal immune-mediated dermatitis occurred in 0.9% (17/1994) of patients. In patients receiving OPDIVO with YERVOY, hypersensitivity syndrome occurred in 0.5% (6/1207) of patients.
limited to, consultation with a neurologist, brain MRI and lumbar puncture. Withhold OPDIVO in patients with new-onset moderate to severe neurologic signs or symptoms and evaluate to rule out other causes. If other etiologies are ruled out, administer corticosteroids and permanently discontinue OPDIVO for immune-mediated encephalitis. In patients receiving OPDIVO monotherapy, encephalitis occurred in 0.2% (3/1994) of patients. Fatal limbic encephalitis occurred in one patient after 7.2 months of exposure despite discontinuation of OPDIVO and administration of corticosteroids. Encephalitis occurred in one patient receiving OPDIVO with YERVOY (0.2%) after 1.7 months of exposure.

Other Immune-Mediated Adverse Reactions

Based on the severity of adverse reaction, permanently discontinue or withhold treatment, administer high-dose corticosteroids, and, if appropriate, initiate hormone-replacement therapy. Across clinical trials of OPDIVO the following clinically significant immune-mediated adverse reactions occurred in <1.0% of patients receiving OPDIVO: uveitis, iritis, pancreatitis, facial and abducens nerve paresis, demyelination, polymyalgia rheumatica, autoimmune neuropathy, Guillain-Barré syndrome, hypopituitarism, systemic inflammatory response syndrome, gastritis, duodenitis, sarcoidosis, histiocytic necrotizing lymphadenitis (Kikuchi lymphadenitis), myositis, myocarditis, rhabdomyolysis, motor dysfunction, vasculitis, and myasthenic syndrome.

Infusion Reactions

OPDIVO can cause severe infusion reactions, which have been reported in <1.0% of patients in clinical trials. Discontinue OPDIVO in patients with Grade 3 or 4 infusion reactions. Interrupt or slow the rate of infusion in patients with Grade 1 or 2. In patients receiving OPDIVO monotherapy, infusion-related reactions occurred in 6.4% (127/1994) of patients. In patients receiving OPDIVO with YERVOY, infusion-related reactions occurred in 2.5% (10/407) of patients.

Complications of Allogeneic HSCT after OPDIVO

Complications, including fatal events, occurred in patients who received allogeneic HSCT after OPDIVO. Outcomes were evaluated in 17 patients from Checkmate 205 and 039, who underwent allogeneic HSCT after discontinuing OPDIVO (15 with reduced-intensity conditioning, 2 with myeloablative conditioning). Thirty-five percent (6/17) of patients died from complications of allogeneic HSCT after OPDIVO. Five deaths occurred in the setting of severe or refractory GVHD. Grade 3 or higher acute GVHD was reported in 29% (5/17) of patients. Hyperacute GVHD was reported in 20% (n=2) of patients. A steroid-requiring febrile syndrome, without an identified infectious cause, was reported in 35% (n=6) of patients. Two cases of encephalitis were reported: Grade 3 (n=1) lymphocytic encephalitis without an identified infectious cause, and Grade 3 (n=1) suspected viral encephalitis. Hepatic veno-occlusive disease (VOD) occurred in one patient, who received reduced-intensity conditioned allogeneic HSCT and died of GVHD and multi-organ failure. Other cases of hepatic VOD after reduced-intensity conditioned allogeneic HSCT have also been reported in patients with lymphoma who received a PD-1 receptor blocking antibody before transplantation. Cases of fatal hyperacute GVHD have also been reported. These complications may occur despite intervening therapy between PD-1 blockade and allogeneic HSCT.

Follow patients closely for early evidence of transplant-related complications such as hyperacute GVHD, severe (Grade 3 to 4) acute GVHD, steroid-requiring febrile syndrome, hepatic VOD, and other immune-mediated adverse reactions, and intervene promptly.

Embryo-Fetal Toxicity

Based on their mechanisms of action, OPDIVO and YERVOY 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 an OPDIVO- or YERVOY- containing regimen and for at least 5 months after the last dose of OPDIVO.

Lactation

It is not known whether OPDIVO or YERVOY 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 an OPDIVO-containing regimen, advise women to discontinue breastfeeding during treatment. Advise women to discontinue nursing during treatment with YERVOY and for 3 months following the final dose.

Serious Adverse Reactions

In Checkmate 037, serious adverse reactions occurred in 41% of patients receiving OPDIVO (n=268). 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 Checkmate 066, serious adverse reactions occurred in 36% of patients receiving OPDIVO (n=206). Grade 3 and 4 adverse reactions occurred in 41% of patients receiving OPDIVO. The most frequent Grade 3 and 4 adverse reactions reported in ≥2% of patients receiving OPDIVO were gamma-glutamyltransferase increase (3.9%) and diarrhea (3.4%). In Checkmate 067, serious adverse reactions (73% and 37%), adverse reactions leading to permanent discontinuation (43% and 14%) or to dosing delays (55% and 28%), and Grade 3 or 4 adverse reactions (72% and 44%) all occurred more frequently in the OPDIVO plus YERVOY arm (n=313) relative to the OPDIVO arm (n=313). The most frequent (≥10%) serious adverse reactions in the OPDIVO plus YERVOY arm and the OPDIVO arm, respectively, were diarrhea (13% and 2.6%), colitis (10% and 1.6%), and pyrexia (10% and 0.6%). In Checkmate 017 and 057, serious adverse reactions occurred in 46% of patients receiving OPDIVO (n=418). The most frequent serious adverse reactions reported in at least 2% of patients receiving OPDIVO were pneumonia, pulmonary embolism, dyspnea, pyrexia, pleural effusion, pneumonitis, and respiratory failure. In Checkmate 025, serious adverse reactions occurred in 47% of patients receiving OPDIVO (n=406). The most frequent serious adverse reactions reported in ≥2% of patients were acute kidney injury, pleural effusion, pneumonia, diarrhea, and hypercalcemia. In Checkmate 025 and 039, among all patients (safety population n=263), adverse reactions leading to discontinuation (4.2%) or to dosing delays (23%) occurred. The most frequent serious adverse reactions reported in ≥1% of patients were infusion-related reaction, pneumonia, pleural effusion, pyrexia, rash and pneumonitis. Ten patients died from causes other than disease progression, including 6 who died from complications of allogeneic HSCT. Serious adverse reactions occurred in 21% of patients in the safety population (n=263) and 27% of patients in the subset of patients
evaluated for efficacy (efficacy population \( n=95 \)). In Checkmate 141, serious adverse reactions occurred in 49% of patients receiving OPDIVO. The most frequent serious adverse reactions reported in at least 2% of patients receiving OPDIVO were pneumonia, dyspnea, respiratory failure, respiratory tract infections, and sepsis. In Checkmate 275, serious adverse reactions occurred in 54% of patients receiving OPDIVO \( n=270 \). The most frequent serious adverse reactions reported in at least 2% of patients receiving OPDIVO were urinary tract infection, sepsis, diarrhea, small intestine obstruction, and general physical health deterioration.

**Common Adverse Reactions**

In Checkmate 037, the most common adverse reaction \( \geq 20\% \) reported with OPDIVO \( n=268 \) was rash \( (21\%) \). In Checkmate 066, the most common adverse reactions \( \geq 20\% \) reported with OPDIVO \( n=206 \) vs dacarbazine \( n=205 \) were fatigue \( (49\% \text{ vs } 39\%) \), musculoskeletal pain \( (32\% \text{ vs } 25\%) \), rash \( (28\% \text{ vs } 12\%) \), and pruritus \( (23\% \text{ vs } 12\%) \). In Checkmate 067, the most common \( \geq 20\% \) adverse reactions in the OPDIVO plus YERVOY arm \( n=313 \) were fatigue \( (59\%) \), rash \( (53\%) \), diaphoresis \( (52\%) \), nausea \( (40\%) \), pyrexia \( (37\%) \), vomiting \( (28\%) \), and dyspnea \( (20\%) \). The most common\( \geq 20\% \) adverse reactions in the OPDIVO \( n=313 \) arm were fatigue \( (53\%) \), rash \( (40\%) \), diaphoresis \( (31\%) \), and nausea \( (28\%) \). In Checkmate 017 and 057, the most common adverse reactions \( \geq 20\% \) in patients receiving OPDIVO \( n=418 \) were fatigue, musculoskeletal pain, cough, dyspnea, and decreased appetite. In Checkmate 025, the most common adverse reactions \( \geq 20\% \) reported in patients receiving OPDIVO \( n=406 \) vs everolimus \( n=397 \) were asthenic conditions \( (56\% \text{ vs } 57\%) \), cough \( (34\% \text{ vs } 38\%) \), nausea \( (28\% \text{ vs } 29\%) \), rash \( (28\% \text{ vs } 36\%) \), dyspnea \( (27\% \text{ vs } 31\%) \), diaphoresis \( (25\% \text{ vs } 32\%) \), constipation \( (23\% \text{ vs } 18\%) \), decreased appetite \( (23\% \text{ vs } 30\%) \), back pain \( (21\% \text{ vs } 16\%) \), and arthralgia \( (20\% \text{ vs } 14\%) \). In Checkmate 205 and 039, among all patients (safety population \( n=263 \)) and the subset of patients in the efficacy population \( n=95 \), respectively, the most common adverse reactions \( \geq 20\% \) were fatigue \( (32\% \text{ vs } 43\%) \), upper respiratory tract infection \( (28\% \text{ vs } 48\%) \), pyrexia \( (24\% \text{ vs } 35\%) \), diaphoresis \( (23\% \text{ vs } 30\%) \), and cough \( (22\% \text{ vs } 35\%) \). In the subset of patients in the efficacy population \( n=95 \), the most common adverse reactions also included rash \( (31\%) \), musculoskeletal pain \( (27\%) \), pruritus \( (25\%) \), nausea \( (23\%) \), arthralgia \( (21\%) \), and peripheral neuropathy \( (21\%) \). In Checkmate 141, the most common adverse reactions \( \geq 10\% \) in patients receiving OPDIVO were cough and dyspnea at a higher incidence than investigator’s choice. In Checkmate 275, the most common adverse reactions \( \geq 20\% \) reported in patients receiving OPDIVO \( n=270 \) were fatigue \( (46\%) \), musculoskeletal pain \( (30\%) \), nausea \( (22\%) \), and decreased appetite \( (22\%) \). In a separate Phase 3 study of YERVOY 3 mg/kg, the most common adverse reactions \( \geq 5\% \) in patients who received YERVOY at 3 mg/kg were fatigue \( (41\%) \), diaphoresis \( (32\%) \), pruritus \( (31\%) \), rash \( (29\%) \), and colitis \( (8\%) \).

**Checkmate Trials and Patient Populations**

- **Checkmate 067** - advanced melanoma alone or in combination with YERVOY; **Checkmate 037 and 066** - advanced melanoma; **Checkmate 017** - squamous non-small cell lung cancer (NSCLC); **Checkmate 057** - non-squamous NSCLC; **Checkmate 025** - renal cell carcinoma; **Checkmate 205/039** - classical Hodgkin lymphoma; **Checkmate 141** - squamous cell carcinoma of the head and neck; **Checkmate 275** - urothelial carcinoma.

Please see U.S. Full Prescribing Information for OPDIVO and YERVOY, including Boxed WARNING regarding immune-mediated adverse reactions for YERVOY.

**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 2014, Ono and Bristol-Myers Squibb 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 us at BMS.com or follow us on LinkedIn, Twitter, YouTube and Facebook.

**About Incyte**

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company’s website at www.incyte.com.

Follow @Incyte on Twitter at https://twitter.com/Incyte.

**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 the compound discussed in this release, either alone or in combination with Opdivo, will be successfully developed or approved for any of the indications described in this release. 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, 2016 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.

**Incyte Corporation Forward-Looking Statement**
Except for the historical information set forth herein, the matters set forth in this press release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: whether and when the planned pivotal trials investigating epacadostat with Opdivo in any of non-small cell lung or head and neck cancers will commence; whether any of these studies will lead to any products that will be approved for use in humans anywhere; whether these planned collaborations will help improve clinical outcomes for patients; whether and when any data from the ECHO program will be available.

These forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: the efficacy or safety of the Incyte’s development pipeline; the results of further research and development; the high degree of risk and uncertainty associated with drug development, clinical trials and regulatory approval processes, other market or economic factors and competitive and technological advances; the possibility that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; our ability to compete against parties with greater financial or other resources; greater than expected expenses; and such other risks detailed from time to time in Incyte’s reports filed with the Securities and Exchange Commission, including our Form 10-K for the year ending December 31, 2016. Incyte disclaims any intent or obligation to update these forward-looking statements.

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