Bristol-Myers Squibb to Present New Data across Multiple Blood Cancers at the 57th Annual Meeting & Exposition of the American Society of Hematology

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Extended follow-up and overall survival update from pivotal ELOQUENT-2 trial, evaluating elotuzumab as combination therapy in relapsed or refractory multiple myeloma, to be presented

New extended follow-up data from Checkmate -039, evaluating Opdivo (nivolumab) in Hodgkin lymphoma, to be presented

Chronic myeloid leukemia health economic data to be presented during oral presentation

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced the presentation of clinical research from its hematology portfolio at the 57th Annual Meeting & Exposition of the American Society of Hematology (ASH) in Orlando, FL, December 5-8. Bristol-Myers Squibb will present data for elotuzumab, an investigational immunostimulatory antibody, in patients with relapsed or refractory (R/R) multiple myeloma (MM); for Opdivo (nivolumab) for an investigational use in patients with R/R classical Hodgkin lymphoma (cHL); and for Sprycel (dasatinib) in chronic myeloid leukemia (CML).

Data to be presented during oral presentations include:

- **ELOQUENT-2**: Extended follow-up and overall survival data from a randomized, open-label, Phase 3 study [Abstract #28] comparing elotuzumab in combination with lenalidomide and dexamethasone versus lenalidomide and dexamethasone alone in patients with R/R MM will be presented on Saturday, December 5, 8:15 a.m. EST. Results from the primary analysis of the ELOQUENT-2 study were published in *The New England Journal of Medicine* on June 2, 2015.

- **Study CA204-009**: A Phase 2, open-label study [Abstract #510] comparing elotuzumab in combination with bortezomib (a proteasome inhibitor) and dexamethasone versus bortezomib and dexamethasone alone in patients with R/R MM will be presented on Monday, December 7, 8:15 a.m. EST.

- **Checkmate -039**: New extended follow-up on the Phase 1 study [Abstract #583] of Opdivo for an investigational use in patients with R/R cHL will be presented December 7, 10:30 a.m. EST. Earlier results from the cHL cohort enrolled in Checkmate -039 were published in *The New England Journal of Medicine* on December 6, 2014.

- **Study CA180-590**: A study [Abstract #876] on the economic burden of adverse events associated with tyrosine kinase inhibitors in patients with CML will be presented on December 7, 5:45 p.m. EST.

“We are proud to present data across our rapidly expanding hematology portfolio that validates our leading Immuno-Oncology approach and leverages our deep scientific expertise with the goal of improving outcomes for patients with hematologic malignancies,” said Michael Giordano, senior vice president, Head of Development, Oncology, Bristol-Myers Squibb.

“Furthermore, we are committed to evaluating a broad range of rational combinations that have the potential to change long-term expectations for patients living with hematologic malignancies.”

The full set of data to be presented by Bristol-Myers Squibb includes:

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<thead>
<tr>
<th>Title</th>
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<tr>
<td><strong>Multiple Myeloma</strong></td>
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<td><strong>ELOQUENT-2 update: A phase 3, randomized, open-label study of elotuzumab in combination with lenalidomide/ dexamethasone in patients with R/R MM: 3-year follow-up</strong></td>
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<td><strong>Elotuzumab plus bortezomib and dexamethasone versus bortezomib and examethasone in patients with R/R MM: 2-year follow-up</strong></td>
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<td><strong>Effects of elotuzumab on soluble SLAMF7 levels in multiple myeloma</strong></td>
<td>Poster presentation</td>
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<td><strong>An ongoing multinational observational study in multiple myeloma (PREAMBLE): Preliminary report on patient survival</strong></td>
<td>Poster presentation</td>
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<td><strong>Economic impact of disease progression (DP) in Medicare patients with multiple myeloma (MM)</strong></td>
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<td><strong>Assessing the economic burden in Medicare patients with multiple myeloma</strong></td>
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**Lymphoma**

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<tr>
<td><strong>Clinical Outcomes in patients with Hodgkin lymphoma responsive to nivolumab in a phase 1 study (CA209-039): Results of extended follow-up</strong></td>
<td>Oral Presentation</td>
<td>Monday, December 7</td>
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**Chronic Myeloid Leukemia**

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<td><strong>Economic burden of adverse events in patients with chronic myelogenous leukemia (CML) treated with BCR-ABL tyrosine kinase inhibitors (TKI)</strong></td>
<td>Oral Presentation</td>
<td>Monday, December 7</td>
<td>5:45-6:00 p.m.</td>
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<td><strong>Dasatinib in patients with chronic phase chronic myeloid leukemia (CML-CP) with persistent, low-grade nonhematologic toxicity to imatinib: Results from DASPERSE (CA180-400)</strong></td>
<td>Poster Presentation</td>
<td>Saturday, December 5</td>
<td>5:30-7:30 p.m.</td>
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<td><strong>Evaluation of cardiovascular disease risk in chronic myelogenous leukemia patients using electronic medical records from community-based oncology practices</strong></td>
<td>Poster Presentation</td>
<td>Monday, December 7</td>
<td>6:00-8:00 p.m.</td>
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**About Elotuzumab**

Elotuzumab is an immunostimulatory antibody that specifically targets Signaling Lymphocyte Activation Molecule Family member 7 (SLAMF7), a cell-surface glycoprotein. SLAMF7 is expressed on myeloma cells independent of cytogenetic abnormalities. SLAMF7 is also expressed on Natural Killer cells, plasma cells, and at lower levels on specific immune cell subsets of differentiated cells within the hematopoietic lineage.

Elotuzumab has a dual mechanism-of-action. It directly activates the immune system through Natural Killer cells via the SLAMF7 pathway. Elotuzumab also targets SLAMF7 on myeloma cells, tagging these malignant cells for Natural Killer cell-mediated destruction via antibody-dependent cellular toxicity.

Bristol-Myers Squibb and AbbVie are co-developing elotuzumab, with Bristol-Myers Squibb solely responsible for commercial activities. Elotuzumab was granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for use in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in patients who have received one to three prior therapies. According to the FDA, Breakthrough Therapy Designation is intended to expedite the development and review of drugs for serious or life-threatening conditions. The criteria for Breakthrough Therapy Designation requires preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy.

**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** is the first PD-1 immune checkpoint inhibitor to receive regulatory approval anywhere in the world in July 2014, and currently has regulatory approval in 40 countries including the United States, Japan, and in the European Union.

**INDICATIONS and IMPORTANT SAFETY INFORMATION for OPDIVO (nivolumab)**

**INDICATIONS**

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

OPDIVO® (nivolumab) as a single agent is indicated for the treatment of patients with unresectable or metastatic, BRAF V600 mutation-positive melanoma and disease progression following ipilimumab and 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.

OPDIVO® (nivolumab), in combination with (ipilimumab), is indicated for the treatment of patients with BRAF V600 wild-type, unresectable or metastatic melanoma. 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.

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.

**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 dermatitis, enterocolitis, hepatitis, pneumonitis, interstitial lung disease, nephritis, colitis, pancreatitis, 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, nephritis, 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**

Immune-mediated pneumonitis or interstitial lung disease, including fatal cases, occurred with OPDIVO treatment. Across the clinical trial experience with solid tumors, fatal immune-mediated pneumonitis occurred with OPDIVO. In addition, in Checkmate 069, there were six patients who died without resolution of abnormal respiratory findings. Monitor patients for signs with radiographic imaging and symptoms of pneumonitis. Administer corticosteroids for Grade 2 or greater pneumonitis. Permanently discontinue for Grade 3 and withhold until resolution for Grade 2. In Checkmate 037, 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: Grade 3 (n=1) and Grade 2 (n=3). In Checkmate 066, immune-mediated pneumonitis occurred in 1.2% (3/268) of patients receiving OPDIVO and in none of the 102 patients receiving dacarbazine: Grade 2 (n=3). In Checkmate 057, immune-mediated pneumonitis, including interstitial lung disease, occurred in 3.4% (10/287) of patients: Grade 3 (n=5), Grade 2 (n=2), and Grade 1 (n=3). In Checkmate 025, pneumonitis, including interstitial lung disease, occurred in 2.7% (21/783) of patients receiving OPDIVO and 18% (73/397) of patients receiving everolimus. Immune-mediated pneumonitis occurred in 4.4% (18/406) of patients receiving OPDIVO: Grade 4 (n=1), Grade 3 (n=4), Grade 2 (n=12), and Grade 1 (n=1). In Checkmate 069, pneumonitis, including interstitial lung disease, occurred in 10% (9/94) of patients receiving OPDIVO in combination with **YERVOY** and 2.2% (1/46) of patients receiving **YERVOY**. Immune-mediated pneumonitis occurred in 6% (6/94) of patients receiving OPDIVO in combination with **YERVOY**: Grade 5 (n=1), Grade 3 (n=2) and Grade 2 (n=3).

**Immune-Mediated Colitis**

Immune-mediated colitis can occur with OPDIVO treatment. Monitor patients for signs and symptoms of colitis. Administer corticosteroids for Grade 2 (of more than 5 days duration), 3, or 4 colitis. As a single agent, withhold OPDIVO for Grade 2 or 3 and permanently discontinue for Grade 4 or recurrent colitis upon restarting OPDIVO. In combination with **YERVOY**, withhold OPDIVO for Grade 2 and permanently discontinue for Grade 3 or 4 or recurrent colitis upon restarting OPDIVO. In Checkmate 037, 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: Grade 3 (n=5) and Grade 2 (n=1). In Checkmate 066, diarrhea or colitis occurred in 28% (58/206) of patients receiving OPDIVO and 25% (52/205) of patients receiving dacarbazine. Immune-mediated colitis occurred in 4.9% (10/206) of patients receiving OPDIVO: Grade 3 (n=1), Grade 2 (n=2), and Grade 1 (n=1). In Checkmate 057, diarrhea or colitis occurred in 2.6% (7/268) of patients receiving OPDIVO: Grade 3 (n=3), Grade 2 (n=2), and Grade 1 (n=2). In Checkmate 025, diarrhea or colitis occurred in 25% (100/406) of patients receiving OPDIVO and 32% (126/397) of patients receiving everolimus. Immune-mediated colitis occurred in 2.4% (7/287) of patients: Grade 3 (n=3), Grade 2 (n=2), and Grade 1 (n=2). In Checkmate 057, diarrhea or colitis occurred in 3.2% (13/406) of patients receiving OPDIVO: Grade 3 (n=5), Grade 2 (n=7), and Grade 1 (n=1). In Checkmate 069, diarrhea or colitis occurred in 5.7% (54/94) of patients receiving OPDIVO in combination with **YERVOY** and 46% (21/46) of patients receiving **YERVOY**. Immune-mediated colitis occurred in 33% (31/94) of patients receiving OPDIVO in combination with **YERVOY**: Grade 4 (n=1), Grade 3 (n=16), Grade 2 (n=9), and Grade 1 (n=5).
In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal (diabetes of ≥7 stools above baseline, fever, ileus, peritoneal signs; Grade 3-5) immune-mediated enterocolitis occurred in 34 (7%) patients. 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 Hepatitis

Immune-mediated hepatitis can occur with OPDIVO treatment. 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 3 or 4 immune-mediated hepatitis. In Checkmate 037, 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; Grade 3 (n=2) and Grade 2 (n=1). In Checkmate 066, there was an increased incidence of liver test abnormalities in the OPDIVO-treated group as compared to the dacarbazine-treated group, with increases in ALT (25% vs. 19%), AST (24% vs. 19%), alkaline phosphatase (21% vs. 14%), and total bilirubin (13% vs. 6%). Immune-mediated hepatitis occurred in 0.9% (2/206) of patients receiving OPDIVO: Grade 3 (n=1) and Grade 2 (n=1). In Checkmate 057, one patient (0.3%) developed immune-mediated hepatitis. In Checkmate 025, there was an increased incidence of liver test abnormalities compared to baseline in AST (33% vs 39%), alkaline phosphatase (32% vs 32%), ALT (22% vs 31%), and total bilirubin (9% vs 3.5%) in the OPDIVO-treated and everolimus-treated groups, respectively. Immune-mediated hepatitis requiring systemic immunosuppression occurred in 1.5% (6/406) of patients receiving OPDIVO: Grade 3 (n=5) and Grade 2 (n=1). In Checkmate 069, immune-mediated hepatitis occurred in 15% (14/94) of patients receiving OPDIVO in combination with YERVOY: Grade 4 (n=3), Grade 3 (n=9), and Grade 2 (n=2).

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 Dermatitis

In a separate Phase 3 study of YERVOY 3 mg/kg, severe, life-threatening, or fatal immune-mediated dermatitis (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis, or rash complicated by full thickness dermal ulceration, or necrotic, bullous, or hemorrhagic manifestations; Grade 3-5) occurred in 13 (2.5%) patients. 1 (0.2%) patient died as a result of toxic epidermal necrolysis. 1 additional patient required hospitalization for severe dermatitis.

### 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 Endocrinopathies

Hypophysitis, adrenal insufficiency, thyroid disorders, and type 1 diabetes mellitus can occur with OPDIVO treatment. Monitor patients for signs and symptoms of hypophysitis, signs and symptoms of adrenal insufficiency during and after treatment, thyroid function prior to and periodically during treatment, and hyperglycemia. Administer corticosteroids for Grade 2 or greater hypophysitis. Withhold for Grade 2 or 3 and permanently discontinue for Grade 4 hypophysitis. Administer corticosteroids for Grade 3 or 4 adrenal insufficiency. Withhold for Grade 2 and permanently discontinue for Grade 3 or 4 adrenal insufficiency. Administer hormone-replacement therapy for hypothyroidism. Initiate medical management for control of hyperthyroidism. Administer insulin for type 1 diabetes. Withhold OPDIVO for Grade 3 and permanently discontinue for Grade 4 hyperglycermia.

In Checkmate 025, hypophysitis occurred in 0.5% (2/406) of patients receiving OPDIVO: Grade 3 (n=1) and Grade 1 (n=1). In Checkmate 069, hypophysitis occurred in 13% (12/94) of patients receiving OPDIVO in combination with YERVOY: Grade 3 (n=2) and Grade 2 (n=10). In Checkmate 037, 066, 057, <1.0% of OPDIVO-treated patients developed adrenal insufficiency. In Checkmate 025, adrenal insufficiency occurred in 2.0% (8/406) of patients receiving OPDIVO: Grade 3 (n=3), Grade 2 (n=4), and Grade 1 (n=1). In Checkmate 069, adrenal insufficiency occurred in 9% (8/94) of patients receiving OPDIVO in combination with YERVOY: Grade 3 (n=3), Grade 2 (n=4), and Grade 1 (n=1). In Checkmate 037, 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 3.0% (8/268) of patients receiving OPDIVO and 1.0% (1/102) of patients receiving chemotherapy. In Checkmate 066, hypothyroidism occurred in 7% (14/206) of patients receiving OPDIVO (Grade 3 (n=1)) and 0.9% (2/205) of patients receiving dacarbazine. Hyperthyroidism occurred in 4.4% (9/206) of patients receiving OPDIVO (Grade 3 (n=1)) and 0.9% (2/205) of patients receiving dacarbazine. In Checkmate 057, Grade 1 or 2 hypothyroidism, including thyroiditis, occurred in 7% (20/287) and elevated TSH occurred in 17% of patients receiving OPDIVO. Grade 1 or 2 hyperthyroidism occurred in 1.4% (4/287) of patients. In Checkmate 025, thyroid disease occurred in 11% (43/406) of patients receiving OPDIVO, including one Grade 3 event, and in 3.0% (12/397) of patients receiving everolimus. Hypothyroidism/thyroiditis occurred in 8% (33/406) of patients receiving OPDIVO: Grade 3 (n=2), Grade 2 (n=17), and Grade 1 (n=14). Hyperthyroidism occurred in 2.5% (10/406) of patients receiving OPDIVO: Grade 2 (n=5) and Grade 1 (n=5). In Checkmate 069, hypothyroidism occurred in 19% (18/94) of patients receiving OPDIVO in combination with YERVOY. All were Grade 1 or 2 in severity except for one patient who experienced Grade 3 autoimmune thyroiditis. Grade 1 hyperthyroidism occurred in 2.1% (2/94) of patients receiving OPDIVO in combination with YERVOY. In Checkmate 066, diabetes mellitus or diabetic ketoacidosis occurred in 1.0% (2/206) of patients receiving OPDIVO and none of the 205 receiving dacarbazine; Grade 3 diabetic ketoacidosis (n=1) and Grade 2 diabetes mellitus (n=1). In Checkmate 025, hyperglycemic adverse events occurred in 9% (37/406) patients. Diabetes mellitus or diabetic ketoacidosis occurred in 1.5% (6/406) of patients receiving OPDIVO: Grade 3 (n=3), Grade 2 (n=2), and Grade 1 (n=1).

In a separate Phase 3 study of YERVOY 3 mg/kg, severe to life-threatening immune-mediated endocrinopathies (requiring hospitalization, urgent medical intervention, or interfering with activities of daily living; Grade 3-4) occurred in 9 (1.8%) patients. All 9 patients had hypopituitarism, and some had additional concomitant endocrinopathies such as adrenal insufficiency, hypogonadism, and hypothyroidism. 6 of the 9 patients were hospitalized for severe endocrinopathies.

### Immune-Mediated Nephritis and Renal Dysfunction
Immune-mediated nephritis can occur with OPDIVO treatment. Monitor patients for elevated serum creatinine prior to and periodically during treatment. For Grade 2 or 3 increased serum creatinine, withhold and administer corticosteroids; if worsening or no improvement occurs, permanently discontinue. Administer corticosteroids for Grade 4 serum creatinine elevation and permanently discontinue. In Checkmate 037, 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 Checkmate 066, there was an increased incidence of elevated creatinine in the OPDIVO-treated group as compared to the dacarbazine-treated group (11% vs. 10%). Grade 3 immune-mediated renal dysfunction occurred in 0.5% (1/206) of patients. In Checkmate 057, Grade 2 immune-mediated renal dysfunction occurred in 0.3% (1/287) of patients receiving OPDIVO. In Checkmate 025, renal injury occurred in 7% (27/396) of patients receiving OPDIVO and 3.0% (12/397) of patients receiving everolimus. Immune-mediated nephritis and renal dysfunction occurred in 3.2% (13/406) of patients receiving OPDIVO: Grade 5 (n=1), Grade 4 (n=1), Grade 3 (n=5), and Grade 2 (n=6). In Checkmate 069, Grade 2 or higher immune-mediated nephritis or renal dysfunction occurred in 2.1% (2/94) of patients. One patient died without resolution of renal dysfunction.

Immune-Mediated Rash

Immune-mediated rash can occur with OPDIVO treatment. Severe rash (including rare cases of fatal toxic epidermal necrolysis) occurred in the clinical program of OPDIVO. For Grade 3 or 4 rash, withhold OPDIVO and permanently discontinue for Grade 4. In Checkmate 057, immune-mediated rash occurred in 6% (17/287) of patients receiving OPDIVO including four Grade 3 cases. In Checkmate 025, rash occurred in 28% (112/406) of patients receiving OPDIVO and 36% (143/397) of patients receiving everolimus. Immune-mediated rash, defined as a rash treated with systemic or topical corticosteroids, occurred in 7% (30/406) of patients receiving OPDIVO: Grade 3 (n=4), Grade 2 (n=7), and Grade 1 (n=19). In Checkmate 069, immune-mediated rash occurred in 37% (35/94) of patients receiving OPDIVO in combination with YERVOY: Grade 3 (n=6), Grade 2 (n=10), and Grade 1 (n=19).

Immune-Mediated Encephalitis

Immune-mediated encephalitis can occur with OPDIVO treatment. 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. Across clinical trials of 8490 patients receiving OPDIVO as a single agent or in combination with YERVOY, <1.0% of patients were identified as having encephalitis. In Checkmate 057, fatal limbic encephalitis occurred in one patient (0.3%) receiving OPDIVO.

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. The following clinically significant immune-mediated adverse reactions occurred in <1.0% of OPDIVO-treated patients: uveitis, pancreatitis, facial and abducens nerve paresis, demyelination, polymyalgia rheumatica, autoimmune neuropathy, Guillain-Barre syndrome, hypopituitarism and systemic inflammatory response syndrome. Across clinical trials of OPDIVO administered as a single agent at doses 3 mg/kg and 10 mg/kg, additional clinically significant, immune-mediated adverse reactions were identified: motor dysfunction, vasculitis, and myasthenic syndrome. Across clinical trials of OPDIVO in combination with YERVOY, the following additional clinically significant, immune-mediated adverse reactions were identified: sarcoidosis, duodenitis, and gastritis.

Infusion Reactions

Severe infusion reactions have been reported in <1.0% of patients in clinical trials of OPDIVO as a single agent. 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 Checkmate 057 and 066, Grade 2 infusion reactions occurred in 1.0% (5/493) of patients receiving OPDIVO. In Checkmate 025, hypersensitivity infusion-related reactions occurred in 6% (25/406) of patients receiving OPDIVO and 1.0% (4/397) of patients receiving everolimus. In Checkmate 069, Grade 2 infusion reactions occurred in 3.2% (3/94) of patients receiving OPDIVO in combination with YERVOY.

Embryofetal 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 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. 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. 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 diaphragm (3.4%). In Checkmate 057, serious adverse reactions occurred in 47% of patients receiving OPDIVO. The most frequent serious adverse reactions reported in ≥2% of patients were pneumonia, pulmonary embolism, dyspnea, pleural effusion, and respiratory failure. In Checkmate 025, serious adverse reactions occurred in 47% of patients receiving OPDIVO. The most frequent serious adverse reactions reported in ≥2% of patients were acute kidney injury, pleural effusion, pneumonia, diarrhea, and hypercalcemia. In Checkmate 069, serious adverse reactions occurred in 62% of patients receiving OPDIVO; the most frequent serious adverse events with
OPDIVO in combination with YERVOY, as compared to YERVOY alone, were colitis (17% vs 9%), diarrhea (9% vs 7%), pyrexia (6% vs 7%), and pneumonitis (5% vs 0).

**Common Adverse Reactions**

In Checkmate 037, the most common adverse reaction (≥20%) reported with OPDIVO was rash (21%). In Checkmate 066, the most common adverse reactions (≥20%) reported with OPDIVO vs dacarbazine were fatigue (49% vs 39%), musculoskeletal pain (32% vs 25%), rash (28% vs 12%), and pruritus (23% vs 12%). In Checkmate 057, the most common adverse reactions (≥20%) reported with OPDIVO were fatigue (49%), musculoskeletal pain (36%), cough (30%), decreased appetite (29%), and constipation (23%). In Checkmate 025, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO vs everolimus were asthenic conditions (56% vs 57%), cough (34% vs 38%), nausea (28% vs 29%), rash (28% vs 36%), dyspnea (27% vs 31%), diarrhea (25% vs 32%), constipation (23% vs 18%), decreased appetite (23% vs 30%), back pain (21% vs 16%), and arthralgia (20% vs 14%). In Checkmate 069, the most common adverse reactions (≥20%) reported in patients receiving OPDIVO in combination with YERVOY vs YERVOY alone were rash (67% vs 57%), pruritus (37% vs 26%), headache (24% vs 20%), vomiting (23% vs 15%), and colitis (22% vs 11%).

In a separate Phase 3 study of YERVOY 3 mg/kg, the most common adverse reactions (≥5%) in patients who received YERVOY at 3 mg/kg were fatigue (41%), diarrhea (32%), pruritus (31%), rash (29%), and colitis (8%).

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

Please see U.S. Full Prescribing Information for OPDIVO

**About Sprycel**

Sprycel was first approved by the FDA in 2006 for the treatment of adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase (CP) who are resistant or intolerant to prior therapy including imatinib. At that time, Sprycel was also approved for adults with Ph+ acute lymphoblastic leukemia (ALL) who are resistant or intolerant to prior therapy. It is the first and only BCR-ABL kinase inhibitor with survival data in its label for CP Ph+ CML patients who are resistant or intolerant to Gleevec® (imatinib mesylate). Sprycel is approved and marketed worldwide for these indications in more than 60 countries.

Sprycel is also an FDA-approved treatment for adults with newly diagnosed CP Ph+ CML (since October 2010). Sprycel received accelerated FDA approval for this indication. Additional country approvals for this indication total more than 50.

**SPRYCEL® (dasatinib) INDICATIONS & IMPORTANT SAFETY INFORMATION**

**INDICATIONS**

SPRYCEL® (dasatinib) is indicated for the treatment of adults with:

- Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase.
- Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib.
- Adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.

**IMPORTANT SAFETY INFORMATION**

**Myelosuppression:**

Treatment with SPRYCEL is associated with severe (NCI CTC Grade 3/4) thrombocytopenia, neutropenia, and anemia, which occur earlier and more frequently in patients with advanced phase CML or Ph+ ALL than in patients with chronic phase CML.

- In patients with chronic phase CML, perform complete blood counts (CBCs) every 2 weeks for 12 weeks, then every 3 months thereafter, or as clinically indicated.
- In patients with advanced phase CML or Ph+ ALL, perform CBCs weekly for the first 2 months and then monthly thereafter, or as clinically indicated.
- Myelosuppression is generally reversible and usually managed by withholding SPRYCEL temporarily and/or dose reduction.
  - In clinical studies, myelosuppression may have also been managed by discontinuation of study therapy.
  - Hematopoietic growth factor has been used in patients with resistant myelosuppression.

**Bleeding Related Events:**

SPRYCEL caused thrombocytopenia in human subjects. In addition, dasatinib caused platelet dysfunction in vitro. In all CML or Ph+ ALL clinical studies, ≥ grade 3 central nervous system (CNS) hemorrhages, including fatalities, occurred in <1% of patients receiving SPRYCEL. Grade 3 or greater gastrointestinal hemorrhage, including fatalities, occurred in 4% of patients and generally required treatment interruptions and transfusions. Other cases of ≥ grade 3 hemorrhage occurred in 2% of patients.

- Most bleeding events in clinical studies were associated with severe thrombocytopenia.
- Concomitant medications that inhibit platelet function or anticoagulants may increase the risk of hemorrhage.

**Fluid Retention:**

SPRYCEL may cause fluid retention. After 5 years of follow-up in the randomized newly diagnosed chronic phase CML study (n=258), grade 3/4 fluid retention was reported in 5% of patients, including 3% of patients with grade 3/4 pleural effusion. In patients with newly diagnosed or imatinib resistant or intolerant chronic phase CML, grade 3/4 fluid retention occurred in 6% of
patients treated with SPRYCEL at the recommended dose (n=548). In patients with advanced phase CML or Ph+ ALL treated with SPRYCEL at the recommended dose (n=304), grade 3/4 fluid retention was reported in 8% of patients, including grade 3/4 pleural effusion reported in 7% of patients.

- Patients who develop symptoms of pleural effusion or other fluid retention, such as new or worsened dyspnea on exertion or at rest, pleuritic chest pain, or dry cough should be evaluated promptly with a chest x-ray or additional diagnostic imaging as appropriate.
- Fluid retention events were typically managed by supportive care measures that may include diuretics or short courses of steroids.
- Severe pleural effusion may require thoracentesis and oxygen therapy.
- Consider dose reduction or treatment interruption

Cardiovascular Events:
After 5 years of follow-up in the randomized newly diagnosed chronic phase CML trial (n=258), the following cardiac adverse events occurred:

- Cardiac ischemic events (3.9% dasatinib vs 1.6% imatinib), cardiac related fluid retention (8.5% dasatinib vs 3.9% imatinib), and conduction system abnormalities, most commonly arrhythmia and palpitations (7.0% dasatinib vs 5.0% imatinib). Two cases (0.8%) of peripheral arterial occlusive disease occurred with imatinib and 2 (0.8%) transient ischemic attacks occurred with dasatinib.

Monitor patients for signs or symptoms consistent with cardiac dysfunction and treat appropriately.

Pulmonary Arterial Hypertension (PAH):
SPRYCEL may increase the risk of developing PAH, which may occur any time after initiation, including after more than 1 year of treatment. Manifestations include dyspnea, fatigue, hypoxia, and fluid retention. PAH may be reversible on discontinuation of SPRYCEL.

- Evaluate patients for signs and symptoms of underlying cardiopulmonary disease prior to initiating SPRYCEL and during treatment. If PAH is confirmed, SPRYCEL should be permanently discontinued.

QT Prolongation:
*In vitro* data suggest that SPRYCEL has the potential to prolong cardiac ventricular repolarization (QT interval).

- Most bleeding events in clinical studies were associated with severe thrombocytopenia.
- Concomitant medications that inhibit platelet function or anticoagulants may increase the risk of hemorrhage.

Severe Dermatologic Reactions:
Cases of severe mucocutaneous dermatologic reactions, including Stevens-Johnson syndrome and erythema multiforme, have been reported in patients treated with SPRYCEL.

- Discontinue permanently in patients who experience a severe mucocutaneous reaction during treatment if no other etiology can be identified.

Tumor Lysis Syndrome (TLS):
TLS has been reported in patients with resistance to prior imatinib therapy, primarily in advanced phase disease.

- Due to potential for TLS, maintain adequate hydration, correct uric acid levels prior to initiating therapy with SPRYCEL, and monitor electrolyte levels.
- Patients with advanced stage disease and/or high tumor burden may be at increased risk and should be monitored more frequently.

Embryo-Fetal Toxicity:
Based on limited human data, SPRYCEL can cause fetal harm when administered to a pregnant woman. Hydrops fetalis, fetal leukopenia and fetal thrombocytopenia have been reported with maternal exposure to SPRYCEL. Transplacental transfer of dasatinib has been measured in fetal plasma and amniotic fluid at concentrations comparable to those in maternal plasma.

- Advise females of reproductive potential to avoid pregnancy, which may include the use of effective contraception, during treatment with SPRYCEL and for 30 days after the final dose.

Lactation:
No data are available regarding the presence of dasatinib in human milk, the effects of the drug on the breastfed infant or the effects of the drug on milk production. However, dasatinib is present in the milk of lactating rats.

- Because of the potential for serious adverse reactions in nursing infants from SPRYCEL, breastfeeding is not recommended during treatment with SPRYCEL and for 2 weeks after the final dose.

Drug Interactions:
SPRYCEL is a CYP3A4 substrate and a weak time-dependent inhibitor of CYP3A4.

- Drugs that may increase SPRYCEL plasma concentrations are:
CYP3A4 inhibitors: Concomitant use of SPRYCEL and drugs that inhibit CYP3A4 should be avoided. If administration of a potent CYP3A4 inhibitor cannot be avoided, close monitoring for toxicity and a SPRYCEL dose reduction should be considered.

Strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, clarithromycin, atazanavir, indinavir, nefazodone, neflinavir, ritonavir, saquinavir, telithromycin, voriconazole). If SPRYCEL must be administered with a strong CYP3A4 inhibitor, a dose decrease or temporary discontinuation should be considered.

- Grapefruit juice may also increase plasma concentrations of SPRYCEL and should be avoided.

Drugs that may decrease SPRYCEL plasma concentrations are:

- CYP3A4 inducers: If SPRYCEL must be administered with a CYP3A4 inducer, a dose increase in SPRYCEL should be considered.

- Strong CYP3A4 inducers (eg, dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, phenobarbital) should be avoided. Alternatively, agents with less enzyme induction potential should be considered. If the dose of SPRYCEL is increased, the patient should be monitored carefully for toxicity.

- St John's Wort may decrease SPRYCEL plasma concentrations unpredictably and should be avoided.

- Antacids may decrease SPRYCEL drug levels. Simultaneous administration of SPRYCEL and antacids should be avoided. If antacid therapy is needed, the antacid dose should be administered at least 2 hours prior to or 2 hours after the dose of SPRYCEL.

- H₂ antagonists/proton pump inhibitors (eg, famotidine and omeprazole): Long-term suppression of gastric acid secretion by use of H₂ antagonists or proton pump inhibitors is likely to reduce SPRYCEL exposure. Therefore, concomitant use of H₂ antagonists or proton pump inhibitors with SPRYCEL is not recommended.

Drugs that may have their plasma concentration altered by SPRYCEL are:

- CYP3A4 substrates (eg, simvastatin) with a narrow therapeutic index should be administered with caution in patients receiving SPRYCEL.

### Adverse Reactions:

- In newly diagnosed chronic phase CML patients:
  - Drug-related serious adverse events (SAEs) were reported for 16.7% of SPRYCEL-treated patients. Serious adverse reactions reported in ≥5% of patients included pleural effusion (5%).
  - Most common adverse reactions (≥15%) included myelosuppression, fluid retention, and diarrhea.

- In patients resistant or intolerant to prior imatinib therapy:
  - Drug-related SAEs were reported for 26.1% of Sprycel-treated patients treated at the recommended dose of 100 mg once daily in the randomized dose-optimization trial of patients with chronic phase CML resistant or intolerant to prior imatinib therapy. Serious adverse reactions reported in ≥5% of patients included pleural effusion (10%).
  - Most common adverse reactions (≥15%) included myelosuppression, fluid retention events, diarrhea, headache, fatigue, dyspnea, skin rash, nausea, hemorrhage and musculoskeletal pain.

Please see the full Prescribing Information here.

### 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 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 elotuzumab will receive regulatory approval or, if approved, that it will become a commercially successful product or that Opdivo or Sprycel will receive approval for any additional indications described herein or, if approved, become commercially successful in such indications. 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.