Bristol-Myers Squibb Demonstrates Commitment to Hematology and Advancing Research and Development Across Multiple Blood Cancers Through Immuno-Oncology Leadership at the 20th Congress of the European Hematology Association

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Results from two trials (ELOQUENT-2 & 009) in which elotuzumab’s novel mechanism of action demonstrated a significant and sustained reduction in the risk of disease progression or death in patients with relapsed or refractory multiple myeloma to be presented

Updated data from Opdivo (nivolumab) early-stage research in relapsed or refractory lymphoid malignancies to be presented

Real-world data for multiple compounds which advance the understanding of chronic myeloid leukemia and multiple myeloma patient care to be presented

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) today announced the presentation of clinical research from its hematology portfolio at the 20th Congress of the European Hematology Association (EHA) in Vienna, Austria from June 11-14. Bristol-Myers Squibb will present data for elotuzumab, an investigational immunostimulatory antibody, in relapsed or refractory multiple myeloma; Opdivo (nivolumab), in patients with relapsed or refractory lymphoid malignancies; and Sprycel (dasatinib), in chronic myeloid leukemia.

Data to be presented at EHA exemplify Bristol-Myers Squibb’s commitment to advancing the treatment of blood cancers through its experience in hematology and its transformative science of Immuno-Oncology.

Key oral presentations include:

- **ELOQUENT-2**: A Phase 3, open-label study [Abstract #S471] comparing elotuzumab in combination with lenalidomide and dexamethasone (ELd) versus lenalidomide and dexamethasone alone (Ld) in patients with relapsed or refractory multiple myeloma, will be featured in the EHA press briefing on Friday, June 12 at 8:30 a.m. CEST and will be presented during the Presidential Symposium, also on June 12, at 3:45 p.m. CEST. The ELOQUENT-2 study was published in the *New England Journal of Medicine* on June 2.

- **Study 009**: A Phase 2, open-label study [Abstract #S103] comparing elotuzumab in combination with bortezomib (a proteasome inhibitor) and dexamethasone versus bortezomib and dexamethasone in patients with relapsed or refractory multiple myeloma will be presented in an oral session on June 12 at 12:00 p.m. CEST.

- **PREAMBLE**: A preliminary analysis of an ongoing, multinational, observational study [Abstract #S148] evaluating the real-world clinical effectiveness of standard treatments, including immunomodulatory drugs (IMiDs) and proteasome inhibitors (PIs), in patients with relapsed or refractory multiple myeloma will be presented in an oral session on June 12 at 12:00 p.m. CEST.

- **CheckMate -039**: Updated data from a Phase 1 study [Abstract #S808] evaluating the safety, tolerability and potential efficacy of Opdivo in several hematologic malignancies, including classical Hodgkin Lymphoma will be presented in an oral session on Sunday, June 14 at 8:45 a.m. CEST.

“Bristol-Myers Squibb is leveraging its broad experience in oncology and leading Immuno-Oncology science to develop a portfolio of innovative therapies, including a novel modality for multiple myeloma, because we believe patients with blood cancers deserve more,” said Michael Giordano, senior vice president, Head of Development, Oncology, Bristol-Myers Squibb.
“These data at EHA illustrate our commitment to transforming survival expectations for more patients with a variety of 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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<tbody>
<tr>
<td><strong>Multiple Myeloma</strong></td>
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<tr>
<td>An Ongoing Multinational Observational Study in Multiple Myeloma (PREAMBLE): A Preliminary Report of Disease Impact on Quality of Life Abstract #S148</td>
<td>Oral Presentation Friday, June 12 12:00-12:15 p.m. CEST</td>
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<td>A Randomized, Open-label Phase 2 Study of Bortezomib/Dexamethasone with or without Elotuzumab in Patients with Relapsed/Refractory Multiple Myeloma Abstract #S103</td>
<td>Oral Presentation Friday, June 12 12:00-12:15 p.m. CEST</td>
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<tr>
<td>ELOQUENT-2: A Phase 3, Randomized, Open-label Study of Lenalidomide/Dexamethasone with or without Elotuzumab in Patients with Relapsed/Refractory Multiple Myeloma Abstract #S471</td>
<td>Presidential Symposium Friday, June 12 3:45-4:00 p.m. CEST</td>
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<td><strong>Lymphoma</strong></td>
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<td>Nivolumab in Patients with Relapsed or Refractory Lymphoid Malignancies and Classical Hodgkin Lymphoma: Updated Safety and Efficacy Results of a Phase 1 Study (CA209-039) Abstract #S80</td>
<td>Oral Presentation Sunday, June 14 8:45-9:00 a.m. CEST</td>
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<td><strong>Chronic Myeloid Leukemia</strong></td>
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<td>Cardiovascular (CV) and Pulmonary Adverse Events (AEs) in Patients (Pts) Treated with BCR-ABL Tyrosine Kinase Inhibitors (TKIs): Updated Analysis from the FDA Adverse Event Reporting System (FAERS) Abstract #P601</td>
<td>Poster Presentation Saturday, June 13 5:15-6:45 p.m. CEST</td>
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<td>Cardiovascular (CV)-Related Hospitalization in Patients with Chronic-Phase Chronic Myeloid Leukemia (CP-CML) in SIMPLICITY, a Prospective Observational Study Abstract #E1099</td>
<td>Epster Presentation Available to view Friday, June 12, 9:30 a.m. to Saturday, June 13, 6:45 p.m. CEST</td>
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<td>Efficacy and Safety of Dasatinib vs. Imatinib in Latin American Subpopulation from the DASISION Trial in Patients with Newly Diagnosed Chronic Myeloid Leukemia (CML) in Chronic Phase (CP) Abstract #E1119</td>
<td>Epster Presentation Available to view Friday, June 12, 9:30 a.m. to Saturday, June 13, 6:45 p.m. CEST</td>
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<td>Estimated Glomerular Filtration Rates of Chronic Myeloid Leukemia (CML) Patients Treated with Tyrosine Kinase Inhibitors (TKIs) in Dasatinib Trials: DASISION (CA180-056), CA180-034, And CA180-035 Abstract #E1100</td>
<td>Epster Presentation Available to view Friday, June 12, 9:30 a.m. to Saturday, June 13, 6:45 p.m. CEST</td>
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**About Elotuzumab**

Elotuzumab is an investigational immunostimulatory antibody targeted against Signaling Lymphocyte Activation Molecule (SLAMF7), a cell-surface glycoprotein that is highly and uniformly expressed on myeloma cells and Natural Killer (NK) cells, but is not detected on normal solid tissues or on hematopoietic stem cells. Elotuzumab is being investigated to determine whether the compound may selectively target myeloma cells. It is believed that elotuzumab works through a dual mechanism of action: binding to SLAMF7 on NK cells, directly activating them and binding to SLAMF7 on myeloma cells, flagging them for NK cell recognition and destruction.

In May 2014, the U.S. Food and Drug Administration (FDA) granted elotuzumab Breakthrough Therapy Designation for use in combination with one of the chemotherapy treatments for multiple myeloma (lenalidomide, used in combination with dexamethasone) in patients who have received one or more prior treatments. Elotuzumab is an investigational compound, and its safety and efficacy have not been evaluated by the FDA or any other health authority.

Bristol-Myers Squibb and AbbVie are co-developing elotuzumab, with Bristol-Myers Squibb solely responsible for commercial activities.

**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.

In May 2014, the FDA granted Opdivo Breakthrough Therapy Designation for the treatment of patients with Hodgkin Lymphoma after failure of autologous stem cell transplant and brentuximab. 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 with progression on or after platinum-based chemotherapy.

OPDIVO (nivolumab) IMPORTANT SAFETY INFORMATION

Immune-Mediated Pneumonitis

- Severe pneumonitis or interstitial lung disease, including fatal cases, occurred with OPDIVO treatment. Across the clinical trial experience in 691 patients with solid tumors, fatal immune-mediated pneumonitis occurred in 0.7% (5/691) of patients receiving OPDIVO; no cases occurred in Trial 1 or Trial 3. In Trial 1, pneumonitis, including interstitial lung disease, occurred in 3.4% (9/268) of patients receiving OPDIVO and none of the 102 patients receiving chemotherapy. Immune-mediated pneumonitis occurred in 2.2% (6/268) of patients receiving OPDIVO; one with Grade 3 and five with Grade 2. In Trial 3, immune-mediated pneumonitis occurred in 6% (7/117) of patients receiving OPDIVO, including, five Grade 3 and two Grade 2 cases. Monitor patients for signs and symptoms of pneumonitis. Administer corticosteroids for Grade 2 or greater pneumonitis. Permanently discontinue OPDIVO for Grade 3 or 4 and withhold OPDIVO until resolution for Grade 2.

Immune-Mediated Colitis

- In Trial 1, diarrhea or colitis occurred in 21% (57/268) of patients receiving OPDIVO and 18% (18/102) of patients receiving chemotherapy. Immune-mediated colitis occurred in 2.2% (6/268) of patients receiving OPDIVO; five with Grade 3 and one with Grade 2. In Trial 3, diarrhea occurred in 21% (24/117) of patients receiving OPDIVO. Grade 3 immune-mediated colitis occurred in 0.9% (1/117) of patients. Monitor patients for immune-mediated colitis. Administer corticosteroids for Grade 2 (of more than 5 days duration), 3, or 4 colitis. Withhold OPDIVO for Grade 2 or 3. Permanently discontinue OPDIVO for Grade 4 colitis or recurrent colitis upon restarting OPDIVO.

Immune-Mediated Hepatitis

- In Trial 1, there was an increased incidence of liver test abnormalities in the OPDIVO-treated group as compared to the chemotherapy-treated group, with increases in AST (28% vs 12%), alkaline phosphatase (22% vs 13%), ALT (16% vs 5%), and total bilirubin (9% vs 0). Immune-mediated hepatitis occurred in 1.1% (3/268) of patients receiving OPDIVO; two with Grade 3 and one with Grade 2. In Trial 3, the incidences of increased liver test values were AST (16%), alkaline phosphatase (14%), ALT (12%), and total bilirubin (2.7%). Monitor patients for abnormal liver tests prior to and periodically during treatment. Administer corticosteroids for Grade 2 or greater transaminase elevations. Withhold OPDIVO for Grade 2 and permanently discontinue OPDIVO for Grade 3 or 4 immune-mediated hepatitis.

Immune-Mediated Nephritis and Renal Dysfunction

- In Trial 1, there was an increased incidence of elevated creatinine in the OPDIVO-treated group as compared to the chemotherapy-treated group (13% vs 9%). Grade 2 or 3 immune-mediated nephritis or renal dysfunction occurred in 0.7% (2/268) of patients. In Trial 3, the incidence of elevated creatinine was 22%. Immune-mediated renal dysfunction (Grade 2) occurred in 0.9% (1/117) of patients. Monitor patients for elevated serum creatinine prior to and periodically during treatment. For Grade 2 or 3 serum creatinine elevation, withhold OPDIVO and administer corticosteroids; if worsening or no improvement occurs, permanently discontinue OPDIVO. Administer corticosteroids for Grade 4 serum creatinine elevation and permanently discontinue OPDIVO.

Immune-Mediated Hypothyroidism and Hyperthyroidism

- In Trial 1, Grade 1 or 2 hypothyroidism occurred in 8% (21/268) of patients receiving OPDIVO and none of the 102 patients receiving chemotherapy. Grade 1 or 2 hyperthyroidism occurred in 3% (8/268) of patients receiving OPDIVO and 1% (1/102) of patients receiving chemotherapy. In Trial 3, hypothyroidism occurred in 4.3% (5/117) of patients receiving OPDIVO. Hyperthyroidism occurred in 1.7% (2/117) of patients, including one Grade 2 case. Monitor thyroid function prior to and periodically during treatment. Administer thyroid hormone replacement therapy for hypothyroidism. Initiate medical management for control of hyperthyroidism.

Other Immune-Mediated Adverse Reactions

- In Trial 1 and 3 (n=385), the following clinically significant immune-mediated adverse reactions occurred in <2% of OPDIVO-treated patients: adrenal insufficiency, uveitis, pancreatitis, facial and abducens nerve paresis, demyelination, autoimmune neuropathy, motor dysfunction, and vasculitis. Across clinical trials of OPDIVO administered at doses 3 mg/kg and 10 mg/kg, additional clinically significant, immune-mediated adverse reactions were identified: hypophysitis, diabetic ketoacidosis, hypopituitarism, Guillain-Barré syndrome, and myasthenic syndrome. Based on the severity of adverse reaction, withhold OPDIVO, administer high-dose corticosteroids, and, if appropriate, initiate hormone-replacement therapy.

Embryofetal Toxicity

- Based on its mechanism of action, OPDIVO can cause fetal harm when administered to a pregnant woman. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with OPDIVO and for at least 5 months after the last dose of OPDIVO.

Lactation

- It is not known whether OPDIVO is present in human milk. Because many drugs, including antibodies, are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from OPDIVO, advise women to discontinue breastfeeding during treatment.

Serious Adverse Reactions
• In Trial 1, serious adverse reactions occurred in 41% of patients receiving OPDIVO. Grade 3 and 4 adverse reactions occurred in 42% of patients receiving OPDIVO. The most frequent Grade 3 and 4 adverse drug reactions reported in 2% to <5% of patients receiving OPDIVO were abdominal pain, hyponatremia, increased aspartate aminotransferase, and increased lipase.

• In Trial 3, serious adverse reactions occurred in 59% of patients receiving OPDIVO. The most frequent serious adverse drug reactions reported in ≥2% of patients were dyspnea, pneumonia, chronic obstructive pulmonary disease exacerbation, pneumonitis, hypercalcemia, pleural effusion, hemoptysis, and pain.

Common Adverse Reactions

• The most common adverse reactions (≥20%) reported with OPDIVO in Trial 1 were rash (21%) and in Trial 3 were fatigue (50%), dyspnea (38%), musculoskeletal pain (36%), decreased appetite (35%), cough (32%), nausea (29%), and constipation (24%).

Please see U.S. Full Prescribing Information for OPDIVO.

About Sprycel

Sprycel is a prescription medicine used to treat adults who have newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase. The effectiveness of Sprycel in these patients is based on a study that measured two types of response to treatment (cytogenetic and molecular) by one year. The study is ongoing to find out how Sprycel works over a longer period of time. Sprycel is also indicated for adults with Ph+ CML who are no longer benefiting from, or did not tolerate, other treatment including Gleevec® (imatinib mesylate).

SPRYCEL® (dasatinib) INDICATIONS & IMPORTANT SAFETY INFORMATION

INDICATIONS

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

• Newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase. The effectiveness of SPRYCEL is based on cytogenetic and major molecular response rates. The trial is ongoing and further data will be required to determine long-term outcome
• Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib
• Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy

IMPORTANT SAFETY INFORMATION

Myelosuppression:

Treatment with SPRYCEL® (dasatinib) can cause severe (NCI CTC Grade 3/4) thrombocytopenia, neutropenia, and anemia. Their occurrence is more frequent in patients with advanced phase CML or Ph+ ALL than in chronic phase CML. Myelosuppression was reported in patients with normal baseline laboratory values as well as in patients with pre-existing laboratory abnormalities.

• Perform complete blood counts (CBCs) weekly for the first 2 months and then monthly thereafter, or as clinically indicated
• Myelosuppression was generally reversible and usually managed by dose interruption, dose reduction, or discontinuation
• Hematopoietic growth factor has been used in patients with resistant myelosuppression

Bleeding Related Events:

SPRYCEL caused platelet dysfunction in vitro and thrombocytopenia in humans. In all clinical trials, severe central nervous system (CNS) hemorrhage, including fatalities, occurred in 1% of patients receiving SPRYCEL. Severe gastrointestinal hemorrhage, including fatalities, occurred in 4% of patients and generally required treatment interruptions and transfusions. Other cases of severe hemorrhage occurred in 2% of patients.

• Most bleeding events were associated with severe thrombocytopenia. Exercise caution in patients required to take medications that inhibit platelet function or anticoagulants

Fluid Retention:

SPRYCEL is associated with fluid retention. In clinical trials, fluid retention was severe in up to 10% of patients. Severe ascites, pulmonary edema, and generalized edema were each reported in ≤1% of patients.

• Patients who develop symptoms suggestive of pleural effusion, such as dyspnea or dry cough, should be evaluated by chest X-ray
• Severe pleural effusion may require thoracentesis and oxygen therapy
• Fluid retention was typically managed by supportive care measures that included diuretics or short courses of steroids

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

- In 865 patients with leukemia treated with SPRYCEL in five phase 2 single-arm studies, the maximum mean changes in QTcF (90% upper bound CI) from baseline ranged from 7.0 ms to 13.4 ms.
- In clinical trials of patients treated with SPRYCEL (N=2440), 16 patients (1%) had QTc prolongation as an adverse reaction. Twenty-two patients (1%) experienced a QTcF>500 ms.
- Administer SPRYCEL with caution to patients who have or may develop prolongation of QTc, including patients with hypokalemia, hypomagnesemia, or congenital long QT syndrome and patients taking antiarrhythmic drugs, other medicinal products that lead to QT prolongation, and cumulative high-dose anthracycline therapy.
  - Correct hypokalemia or hypomagnesemia prior to SPRYCEL administration.

**Congestive Heart Failure, Left Ventricular Dysfunction, and Myocardial Infarction:**
Cardiac adverse reactions were reported in 7% of 258 patients taking SPRYCEL, including 1.6% of patients with cardiomyopathy, heart failure congestive, diastolic dysfunction, fatal myocardial infarction, and left ventricular dysfunction.

- 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 one 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.

**Use in Pregnancy:**
SPRYCEL may cause fetal harm when administered to a pregnant woman. There are no adequate and well-controlled studies of SPRYCEL in pregnant women.

- Women of childbearing potential should be advised of the potential hazard to the fetus and to avoid becoming pregnant when taking SPRYCEL.

**Nursing Mothers:**
It is unknown whether SPRYCEL is excreted in human milk.

- Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue SPRYCEL.

**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, nefinavir, 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. Alternative 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 an 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:**
The safety data reflect exposure to SPRYCEL in 258 patients with newly diagnosed chronic phase CML in a clinical trial.
(minimum of 36 months follow up; median duration of therapy was 37 months), and in 2182 patients with imatinib-resistant or -intolerant CML or Ph+ ALL in clinical trials (1520 patients had a minimum of 2 years follow up and 662 patients with chronic phase CML had a minimum of 60 months follow up).

The majority of SPRYCEL-treated patients experienced adverse reactions at some time. Patients aged 65 years and older are more likely to experience toxicity. In the newly diagnosed chronic phase CML trial, the cumulative discontinuation rate was 9% with a minimum of 36 months follow up. In patients resistant or intolerant to prior imatinib therapy, the discontinuation rate for SPRYCEL at 2 years for adverse reactions was: 15% of patients in chronic phase CML (all doses), 16% of patients in accelerated phase CML, 15% of patients in myeloid blast phase CML, 8% in lymphoid blast phase CML, and 8% in Ph+ ALL. In patients resistant or intolerant to prior imatinib therapy with chronic phase CML (minimum 60 months follow up), the rate of discontinuation for adverse reactions was 18% in patients treated with 100 mg once daily.

- In newly diagnosed chronic phase CML patients:
  - The most frequently reported serious adverse reactions included pleural effusion (4%), hemorrhage (2%), congestive heart failure (1%), pulmonary hypertension (1%), and pyrexia (1%)
  - The most frequently reported adverse reactions (reported in ≥10% of patients) included myelosuppression, fluid retention events (pleural effusion and superficial localized edema), diarrhea, headache, musculoskeletal pain, rash, and nausea
  - Grade 3/4 laboratory abnormalities included neutropenia (24%), thrombocytopenia (19%), anemia (12%), hypophosphatemia (7%), hypocalcemia (3%), elevated bilirubin (1%), and elevated creatinine (1%)

- In patients resistant or intolerant to prior imatinib therapy:
  - The most frequently reported serious adverse reactions included pleural effusion (11%), gastrointestinal bleeding (4%), febrile neutropenia (4%), dyspnea (3%), pneumonia (3%), pyrexia (3%), diarrhea (3%), infection (2%), congestive heart failure/cardiac dysfunction (2%), pericardial effusion (1%), and CNS hemorrhage (1%)
  - The most frequently reported adverse reactions (reported in ≥20% of patients) included myelosuppression, fluid retention events, diarrhea, headache, dyspnea, skin rash, fatigue, nausea, and hemorrhage
  - Grade 3/4 hematologic laboratory abnormalities in chronic phase CML patients resistant or intolerant to prior imatinib therapy who received SPRYCEL 100 mg once daily with a minimum follow up of 60 months included neutropenia (36%), thrombocytopenia (24%) and anemia (13%). Other grade 3/4 laboratory abnormalities included: hypophosphatemia (10%) and hypokalemia (2%)
    - Among chronic phase CML patients with resistance or intolerance to prior imatinib therapy, cumulative Grade 3 or 4 cytopenias were similar at 2 and 5 years including: neutropenia (36% vs 36%), thrombocytopenia (23% vs 24%), and anemia (13% vs 13%)
  - Grade 3/4 elevations of transaminase or bilirubin and Grade 3/4 hypocalcemia, hypokalemia, and hypophosphatemia were reported in patients with all phases of CML
    - Elevations in transaminase or bilirubin were usually managed with dose reduction or interruption
    - Patients developing Grade 3/4 hypocalcemia during the course of SPRYCEL therapy often had recovery with oral calcium supplementation

Please see the full Prescribing Information http://packageinserts.bms.com/pi/pi_sprycel.pdf.

**Immu-no-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 elotuzumab will receive regulatory approval 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.

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English

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