Bristol-Myers Squibb Receives European Commission Approval for Revlimid® (lenalidomide) in Combination with Rituximab for the Treatment of Adult Patients with Previously Treated Follicular Lymphoma

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Revlimid plus rituximab is the first chemotherapy-free combination regimen approved in Europe for patients with follicular lymphoma who have relapsed or did not respond to previous treatment

Approval was based on data from the phase 3 AUGMENT study, which showed statistically significant improvements in median progression-free survival in patients treated with the combination over rituximab-placebo monotherapy

PRINCETON, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE: BMY) today announced that the European Commission (EC) has approved a new indication for Revlimid (lenalidomide), in combination with rituximab (anti-CD20 antibody), for the treatment of adult patients with previously treated follicular lymphoma (FL) (Grade 1-3a). This combination of Revlimid and rituximab (R²) is the first chemotherapy-free combination regimen approved for patients with FL by the EC.

“This approval is a significant milestone for patients with follicular lymphoma whose disease is not responding to current therapy or has returned following prior treatment. In the phase 3 AUGMENT study, patients receiving R² experienced extended periods of disease remission versus patients receiving rituximab plus placebo,” said Nadim Ahmed, President of Hematology at Bristol-Myers Squibb.

FL is a subtype of indolent, but incurable, non-Hodgkin lymphoma (NHL) which is associated with immune system dysfunction.¹,² There remains an unmet medical need for novel treatments for patients who have relapsed or become refractory to their previous treatment. It has been hypothesized that the combination therapy, R², works with the patient’s immune system using the immunomodulatory properties of Revlimid along with the CD20 antibody-targeted mechanism of action of rituximab in order to help the patient’s own immune system fight the cancer.³

“Immune dysfunction is a defining aspect of indolent NHL, including follicular lymphoma,” said Prof. John Gribben, President of the European Hematology Association and Centre for Haemato-Oncology, Barts Cancer Institute, in England. “By utilizing the patient’s own immune system, R² represents a new approach to treatment in follicular lymphoma, giving patients a chemotherapy-free option with demonstrated efficacy.”

The approval of R² is based primarily on results from the randomized, multi-center, double-blind, phase 3 AUGMENT study, which evaluated the efficacy and safety of the R² combination versus rituximab-placebo in patients with previously treated FL (n=295) or marginal zone lymphoma (MZL) (n=63).⁴

In AUGMENT, treatment with R² demonstrated a statistically significant improvement in the primary endpoint of median progression-free survival (PFS) (EMA Censoring Rules), evaluated by an independent review committee, versus rituximab plus placebo. The median PFS was 39.4 months for FL patients treated with R² and 13.8 months for those treated with rituximab-placebo (HR: 0.40; 95% CI, 0.29-0.55; P<0.0001). Median follow-up time was 29.2 months (range, 0.5-50.9) in the intent to treat population (n=295).⁴

In AUGMENT the adverse reactions of any grade observed more frequently in the FL R² arm compared with the placebo/rituximab arm (with at least 2% higher frequency between arms) were neutropenia (58.2%), diarrhea (30.8%), leukopenia (28.8%), constipation (21.9%), cough (21.9%) and fatigue (21.9%).⁴
In addition to AUGMENT, findings from the MAGNIFY study were included as support for the safety and the efficacy of Revlimid® plus rituximab in patients with relapsed or refractory FL, including rituximab refractory FL patients.5

**About Follicular Lymphoma**

Lymphoma is a blood cancer that develops in lymphocytes, a type of white blood cell in the immune system that helps protect the body from infection.6 There are two classes of lymphoma – Hodgkin lymphoma and non-Hodgkin lymphoma (NHL) – each with specific subtypes that determine how the cancer behaves, spreads and should be treated.3,7,8 Other differentiating factors of lymphomas are what type of lymphocyte is affected (T cell or B cell) and how mature the cells are when they become cancerous.8

FL is the most common indolent (slow-growing) form of NHL, accounting for approximately 25% of all NHL patients.9,10 Most patients present with advanced disease when lymphoma-related symptoms appear (e.g., nodal disease, B symptoms, cytopenia) and receive systemic chemoimmunotherapy.9 While FL patients are generally responsive to initial treatment, the disease course is characterized by recurrent relapses over time with shorter remission periods.11

**About AUGMENT**

AUGMENT is a phase 3, randomized, double-blind clinical trial evaluating the efficacy and safety of Revlimid® (lenalidomide) in combination with rituximab (R²) versus rituximab plus placebo in patients with previously treated follicular lymphoma (FL) or marginal zone lymphoma (MZL). AUGMENT included patients diagnosed with MZL or Grade 1, 2 or 3a FL, who were previously treated with at least 1 prior systemic therapy and two previous doses of rituximab.4 Patients were documented relapsed, refractory or progressive disease following systemic therapy, but were not rituximab-refractory.12

The primary endpoint was progression-free survival, defined as the time from date of randomization to the first observation of disease progression or death due to any cause.12 Secondary and exploratory endpoints included overall response rate, durable complete response rate, complete response rate, duration of response, duration of complete response, overall survival, event-free survival and time to next anti-lymphoma therapy.4,12

**Bristol-Myers Squibb: Advancing Cancer Research**

At Bristol-Myers Squibb, patients are at the center of everything we do. The goal of our cancer research is to increase quality, long-term survival and make cure a possibility. We harness our deep scientific experience, cutting-edge technologies and discovery platforms to discover, develop and deliver novel treatments for patients.

Building upon our transformative work and legacy in hematology and Immuno-Oncology that has changed survival expectations for many cancers, our researchers are advancing a deep and diverse pipeline across multiple modalities. In the field of immune cell therapy, this includes registrational chimeric antigen receptor (CAR) T-cell agents for numerous diseases, and a growing early-stage pipeline that expands cell and gene therapy targets, and technologies. We are developing cancer treatments directed at key biological pathways using our protein homeostasis platform, a research capability that has been the basis of our approved therapies for multiple myeloma and several promising compounds in early to mid-stage development. Our scientists are targeting different immune system pathways to address interactions between tumors, the microenvironment and the immune system to further expand upon the progress we have made and help more patients respond to treatment. Combining these approaches is key to delivering new options for the treatment of cancer and addressing the growing issue of resistance to immunotherapy. We source innovation internally, and in collaboration with academia, government, advocacy groups and biotechnology companies, to help make the promise of transformational medicines a reality for patients.

**About Revlimid®**

Revlimid® is approved in Europe and the United States as monotherapy, indicated for the maintenance treatment of adult patients with newly diagnosed multiple myeloma (MM) who have undergone autologous stem cell transplantation. Revlimid® as combination therapy is approved in Europe, in the United States, in Japan and in around 25 other countries for the treatment of adult patients with previously untreated MM who are not eligible for transplant. Revlimid® is also approved in combination with dexamethasone for the treatment of patients with MM who have received at least one prior therapy in nearly 70 countries, encompassing Europe, the Americas, the Middle-East and Asia, and in combination with dexamethasone for the treatment of patients whose disease has progressed after one therapy in Australia and New Zealand.

Revlimid® is also approved in the United States, Canada, Switzerland, Australia, New Zealand and several Latin American countries, as well as Malaysia and Israel, for transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities and in Europe for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk MDS associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.

In addition, Revlimid® is approved in Europe for the treatment of patients with mantle cell lymphoma (MCL) and in the United States for the treatment of patients with MCL whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. In Switzerland, Revlimid® is indicated for the treatment of patients with relapsed or refractory MCL after prior therapy that included bortezomib and chemotherapy/rituximab.

Revlimid® is also approved in the United States in combination with a rituximab product. It is indicated for the treatment of adult patients with previously treated FL and adult patients with previously treated marginal zone lymphoma.

Revlimid® is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

**U.S. FDA-APPROVED INDICATIONS FOR REVLMID®**
REVLIMID® (lenalidomide) in combination with dexamethasone (dex) is indicated for the treatment of adult patients with multiple myeloma (MM).

REVLIMID is indicated as maintenance therapy in adult patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT).

REVLIMID is indicated for the treatment of adult patients with transfusion-dependent anemia due to low- or intermediate-1–risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities.

REVLIMID is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib.

REVLIMID in combination with a rituximab product is indicated for the treatment of adult patients with previously treated follicular lymphoma (FL).

REVLIMID in combination with a rituximab product is indicated for the treatment of adult patients with previously treated marginal zone lymphoma (MZL).

REVLIMID is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

REVLIMID is only available through a restricted distribution program, REVLIMID REMS®.

Important Safety Information

WARNING: EMBRYO-FETAL TOXICITY, HEMATOLOGIC TOXICITY, and VENOUS and ARTERIAL THROMBOEMBOLISM

Embryo-Fetal Toxicity

Do not use REVLIMID during pregnancy. Lenalidomide, a thalidomide analogue, caused limb abnormalities in a developmental monkey study. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide is used during pregnancy, it may cause birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting REVLIMID treatment. Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after REVLIMID treatment. To avoid embryo-fetal exposure to lenalidomide, REVLIMID is only available through a restricted distribution program, the REVLIMID REMS® program.

Information about the REVLIMID REMS program is available at www.celgeneriskmanagement.com or by calling the manufacturer’s toll-free number 1-888-423-5436.

Hematologic Toxicity (Neutropenia and Thrombocytopenia)

REVLIMID can cause significant neutropenia and thrombocytopenia. Eighty percent of patients with del 5q MDS had to have a dose delay/reduction during the major study. Thirty-four percent of patients had to have a second dose delay/reduction. Grade 3 or 4 hematologic toxicity was seen in 80% of patients enrolled in the study. Patients on therapy for del 5q MDS should have their complete blood counts monitored weekly for the first 8 weeks of therapy and at least monthly thereafter. Patients may require dose interruption and/or reduction. Patients may require use of blood product support and/or growth factors.

Venous and Arterial Thromboembolism

REVLIMID has demonstrated a significantly increased risk of deep vein thrombosis (DVT) and pulmonary embolism (PE), as well as risk of myocardial infarction and stroke in patients with MM who were treated with REVLIMID and dexamethasone therapy. Monitor for and advise patients about signs and symptoms of thromboembolism. Advise patients to seek immediate medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Thromboprophylaxis is recommended and the choice of regimen should be based on an assessment of the patient’s underlying risks.

CONTRAINDICATIONS

Pregnancy: REVLIMID can cause fetal harm when administered to a pregnant female and is contraindicated in females who are pregnant. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risk to the fetus.

Severe Hypersensitivity Reactions: REVLIMID is contraindicated in patients who have demonstrated severe hypersensitivity (e.g., angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis) to lenalidomide.

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity: See Boxed WARNINGS.

- Females of Reproductive Potential: See Boxed WARNINGS.
- Males: Lenalidomide is present in the semen of patients receiving the drug. Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking REVLIMID and for up to 4 weeks after discontinuing REVLIMID, even if they have undergone a successful vasectomy. Male patients taking REVLIMID must not donate sperm.
• **Blood Donation:** Patients must not donate blood during treatment with REVIMID and for 4 weeks following discontinuation of the drug because the blood might be given to a pregnant female patient whose fetus must not be exposed to REVIMID.

**REVIMID REMS® Program:** See Boxed WARNINGS. Prescribers and pharmacies must be certified with the REVIMID REMS program by enrolling and complying with the REMS requirements; pharmacies must only dispense to patients who are authorized to receive REVIMID. Patients must sign a Patient-Physician Agreement Form and comply with REMS requirements; female patients of reproductive potential who are not pregnant must comply with the pregnancy testing and contraception requirements and males must comply with contraception requirements.

**Hematologic Toxicity:** REVIMID can cause significant neutropenia and thrombocytopenia. Monitor patients with neutropenia for signs of infection. Advise patients to observe for bleeding or bruising, especially with use of concomitant medications that may increase risk of bleeding. Patients may require a dose interruption and/or dose reduction. **MM:** Monitor complete blood counts (CBC) in patients taking REVIMID + dexamethasone or REVIMID as maintenance therapy, every 7 days for the first 2 cycles, on days 1 and 15 of cycle 3, and every 28 days thereafter. **MDS:** Monitor CBC in patients on therapy for del 5q MDS, weekly for the first 8 weeks of therapy and at least monthly thereafter. See Boxed WARNINGS for further information. **MCL:** Monitor CBC in patients taking REVIMID for MCL weekly for the first cycle (28 days), every 2 weeks during cycles 2-4, and then monthly thereafter. **FL/MZL:** Monitor CBC in patients taking REVIMID for FL or MZL weekly for the first 3 weeks of Cycle 1 (28 days), every 2 weeks during Cycles 2-4, and then monthly thereafter.

**Venous and Arterial Thromboembolism:** See Boxed WARNINGS. Venous thromboembolic events (DVT and PE) and arterial thromboses (MI and CVA) are increased in patients treated with REVIMID. Patients with known risk factors, including prior thrombosis, may be at greater risk and actions should be taken to try to minimize all modifiable factors (e.g., hyperlipidemia, hypertension, smoking). Thromboprophylaxis is recommended and the regimen should be based on the patient’s underlying risks. ESAs and estrogens may further increase the risk of thrombosis and their use should be based on a benefit-risk decision.

**Increased Mortality in Patients With CLL:** In a clinical trial in the first-line treatment of patients with CLL, single-agent REVIMID therapy increased the risk of death as compared to single-agent chlorambucil. Serious adverse cardiovascular reactions, including atrial fibrillation, myocardial infarction, and cardiac failure, occurred more frequently in the REVIMID arm. REVIMID is not indicated and not recommended for use in CLL outside of controlled clinical trials.

**Second Primary Malignancies (SPM):** In clinical trials in patients with MM receiving REVIMID and in patients with FL or MZL receiving REVIMID + rituximab therapy, an increase of hematologic plus solid tumor SPM, notably AML, have been observed. In patients with MM, MDS was also observed. Monitor patients for the development of SPM. Take into account both the potential benefit of REVIMID and risk of SPM when considering treatment.

**Increased Mortality With Pembrolizumab:** In clinical trials in patients with MM, the addition of pembrolizumab to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of patients with MM with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.

**Hepatotoxicity:** Hepatic failure, including fatal cases, has occurred in patients treated with REVIMID + dexamethasone. Pre-existing viral liver disease, elevated baseline liver enzymes, and concomitant medications may be risk factors. Monitor liver enzymes periodically. Stop REVIMID upon elevation of liver enzymes. After return to baseline values, treatment at a lower dose may be considered.

**Severe Cutaneous Reactions:** Severe cutaneous reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported. These events can be fatal. Patients with a prior history of Grade 4 rash associated with thalidomide treatment should not receive REVIMID. Consider REVIMID interruption or discontinuation for Grade 2-3 skin rash. Permanently discontinue REVIMID for Grade 4 rash, exfoliative or bullous rash, or for other severe cutaneous reactions such as SJS, TEN, or DRESS.

**Tumor Lysis Syndrome (TLS):** Fatal instances of TLS have been reported during treatment with REVIMID. The patients at risk of TLS are those with high tumor burden prior to treatment. Closely monitor patients at risk and take appropriate preventive approaches.

**Tumor Flare Reaction (TFR):** TFR has occurred during investigational use of REVIMID for CLL and lymphoma. Monitoring and evaluation for TFR is recommended in patients with MCL, FL, or MZL. Tumor flare may mimic the progression of disease (PD). In patients with Grade 3 or 4 TFR, it is recommended to withhold treatment with REVIMID until TFR resolves to ≤Grade 1. REVIMID may be continued in patients with Grade 1 and 2 TFR without interruption or modification, at the physician’s discretion.

**Impaired Stem Cell Mobilization:** A decrease in the number of CD34+ cells collected after treatment (>4 cycles) with REVIMID has been reported. Consider early referral to transplant center to optimize timing of the stem cell collection.

**Thyroid Disorders:** Both hypothyroidism and hyperthyroidism have been reported. Measure thyroid function before starting REVIMID treatment and during therapy.

**Early Mortality in Patients With MCL:** In another MCL study, there was an increase in early deaths (within 20 weeks); 12.9% in the REVIMID arm versus 7.1% in the control arm. Risk factors for early deaths include high tumor burden, MIPI score at diagnosis, and high WBC at baseline (≥10 x 10⁹/L).

**Hypersensitivity:** Hypersensitivity, including angioedema, anaphylaxis, and anaphylactic reactions to REVIMID has been reported. Permanently discontinue REVIMID for angioedema and anaphylaxis.

**ADVERSE REACTIONS**

**Multiple Myeloma**
In newly diagnosed: The most frequently reported Grade 3 or 4 reactions included neutropenia, anemia, thrombocytopenia, pneumonia, asthenia, fatigue, back pain, hypokalemia, rash, cataract, lymphopenia, dyspnea, DVT, hyperglycemia, and leukopenia. The highest frequency of infections occurred in Arm Rd Continuous (75%) compared to Arm MPT (56%). There were more Grade 3 and 4 serious adverse reactions of infection in Arm Rd Continuous than either Arm MPT or Rd18.

The most common adverse reactions reported in ≥20% (Arm Rd Continuous): diarrhea (45%), anemia (44%), neutropenia (35%), fatigue (33%), back pain (32%), asthenia (28%), insomnia (28%), rash (26%), decreased appetite (23%), cough (23%), dyspnea (22%), pyrexia (21%), peripheral edema (20%), abdominal pain (20%), muscle spasms (20%), and thrombocytopenia (20%).

Maintenance Therapy Post Auto-HSCT: The most frequently reported Grade 3 or 4 reactions in ≥20% (REVLIMID arm) included neutropenia, thrombocytopenia, and leukopenia. The serious adverse reactions of lung infection and neutropenia (more than 4.5%) occurred in the REVLIMID arm.

The most frequently reported adverse reactions in ≥20% (REVLIMID arm) across both maintenance studies (Study 1, Study 2) were neutropenia (79%, 61%), thrombocytopenia (72%, 24%), leukopenia (23%, 32%), anemia (21%, 9%), upper respiratory tract infection (27%, 11%), bronchitis (4%, 47%), nasopharyngitis (2%, 35%), cough (10%, 27%), gastroenteritis (0%, 23%), diarrhea (54%, 39%), rash (32%, 8%), fatigue (23%, 11%), asthenia (0%, 30%), muscle spasm (0%, 33%), and pyrexia (8%, 20%).

After at least one prior therapy: The most common adverse reactions reported in ≥20% (REVLIMID/dex vs dex/placebo): fatigue (44% vs 42%), neutropenia (42% vs 6%), constipation (41% vs 21%), diarrhea (39% vs 27%), muscle cramp (33% vs 21%), anemia (31% vs 24%), pyrexia (27% vs 23%), peripheral edema (26% vs 21%), nausea (26% vs 21%), back pain (26% vs 19%), upper respiratory tract infection (25% vs 16%), dyspnea (24% vs 17%), dizziness (23% vs 17%), thrombocytopenia (22% vs 11%), rash (21% vs 9%), tremor (21% vs 7%), and weight decreased (20% vs 15%).

Myelodysplastic Syndromes

- Grade 3 and 4 adverse events reported in ≥5% of patients with del 5q MDS were neutropenia (53%), thrombocytopenia (50%), pneumonia (7%), rash (7%), anemia (6%), leukopenia (5%), fatigue (5%), dyspnea (5%), and back pain (5%).
- Adverse events reported in ≥15% of del 5q MDS patients (REVLIMID): thrombocytopenia (61.5%), neutropenia (58.8%), diarrhea (49%), pruritus (42%), rash (36%), fatigue (31%), constipation (24%), nausea (24%), nasopharyngitis (23%), arthralgia (22%), pyrexia (21%), back pain (21%), peripheral edema (20%), cough (20%), dizziness (20%), headache (20%), muscle cramp (18%), dyspnea (17%), pharyngitis (16%), epistaxis (15%), asthenia (15%), upper respiratory tract infection (15%).

Mantle Cell Lymphoma

- Grade 3 and 4 adverse events reported in ≥5% of patients treated with REVLIMID in the MCL trial (N=134) included: neutropenia (43%), thrombocytopenia (28%), anemia (11%), pneumonia (9%), leukopenia (7%), fatigue (7%), diarrhea (6%), dyspnea (6%), and febrile neutropenia (6%).
- Adverse events reported in ≥15% of patients treated with REVLIMID in the MCL trial included neutropenia (49%), thrombocytopenia (36%), fatigue (34%), anemia (31%), diarrhea (31%), nausea (30%), cough (28%), pyrexia (23%), rash (22%), dyspnea (18%), pruritus (17%), peripheral edema (16%), constipation (16%), and leukopenia (15%).

Follicular Lymphoma/Marginal Zone Lymphoma

- Fatal adverse reactions occurred in 6 patients (1.5%) receiving REVLIMID + rituximab across both trials. Fatal adverse reactions (1 each) included: cardio-respiratory arrest, arrhythmia, cardiopulmonary failure, multiple organ dysfunction syndrome, sepsis, and acute kidney injury. The most frequent serious adverse reaction that occurred in the REVLIMID + rituximab arm was febrile neutropenia (3.0%).
- Grade 3 and 4 adverse reactions reported in ≥5% of patients treated in the FL/MZL trial with REVLIMID + rituximab were: neutropenia (50%) and leukopenia (7%).
- Adverse reactions reported in ≥15% of patients with FL/MZL treated with REVLIMID + rituximab were: neutropenia (58%), diarrhea (31%), constipation (26%), cough (24%), fatigue (22%), rash (22%), pyrexia (21%), leukopenia (20%), pruritus (20%), upper respiratory tract infections (18%), abdominal pain (18%), anemia (16%), headache (15%), thrombocytopenia (15%).

DRUG INTERACTIONS

Periodically monitor digoxin plasma levels due to increased Cmax and AUC with concomitant REVLIMID therapy. Patients taking concomitant therapies such as erythropoietin-stimulating agents or estrogen-containing therapies may have an increased risk of thrombosis. It is not known whether there is an interaction between dexamethasone and warfarin. Close monitoring of PT and INR is recommended in patients with MM taking concomitant warfarin.

USE IN SPECIFIC POPULATIONS

- Pregnancy: See Boxed WARNINGS: If pregnancy does occur during treatment, immediately discontinue the drug and refer patient to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling. There is a REVLIMID pregnancy exposure registry that monitors pregnancy outcomes in females exposed to REVLIMID during pregnancy as well as female partners of male patients who are exposed to REVLIMID. This registry is also used to understand the root cause for the pregnancy. Report any suspected fetal exposure to REVLIMID to the FDA via the MedWatch program at 1-800-FDA-1088 and also to Celgene Corporation at 1-888-423-5436.

- Lactation: There is no information regarding the presence of lenalidomide in human milk; the effects of REVLIMID on the breastfed infant, or the effects of REVLIMID on milk production. Because many drugs are excreted in human milk and because of the potential for adverse reactions in breastfed infants from REVLIMID, advise female patients not to breastfeed during treatment with REVLIMID.

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• Renal Impairment: Adjust the starting dose of REVLIMID based on the creatinine clearance value and for patients on dialysis.

Please see full Prescribing Information, including Boxed WARNINGS, for REVLIMID.

For more information, please see the full SMPC related to the EC approval.

Please see the rituximab full Prescribing Information for Important Safety Information at www.rituxan.com.

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, Facebook and Instagram.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 regarding, among other things, the research, development and commercialization of pharmaceutical products. All statements that are not statements of historical facts are, or may be deemed to be, forward-looking statements. Such forward-looking statements are based on historical performance and current expectations and projections about our future financial results, goals, plans and objectives and involve inherent risks, assumptions and uncertainties, including internal or external factors that could delay, divert or change any of them in the next several years, that are difficult to predict, may be beyond our control and could cause our future financial results, goals, plans and objectives to differ materially from those expressed in, or implied by, the statements. These risks, assumptions, uncertainties and other factors include, among others, that the outcome of pricing and reimbursement negotiations in individual countries in Europe may delay or limit the commercial potential of Revlimid (lenalidomide), in combination with rituximab (anti-CD20 antibody), for the additional indication described in this release and whether Revlimid (lenalidomide), in combination with rituximab (anti-CD20 antibody), for such additional indication described in this release will be commercially successful. No forward-looking statement can be guaranteed. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect Bristol-Myers Squibb’s business and market, particularly those identified in the cautionary statement and risk factors discussion in Bristol-Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2018, as updated by our subsequent Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and other filings with the Securities and Exchange Commission. The forward-looking statements included in this document are made only as of the date of this document and except as otherwise required by applicable law, Bristol-Myers Squibb undertakes no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise.


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