June 19, 2017

Celgene Announces Clinical Data Evaluating Broad Range of Blood Cancers to Be Presented at EHA 2017

Presentations highlight innovative research in multiple disease areas including multiple myeloma, lymphoma, leukemia, myelodysplastic syndromes and beta-thalassemia

BOUDRY, Switzerland--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced that data from a broad range of company-sponsored and investigator-initiated studies evaluating Celgene investigational agents and investigational uses of marketed products will be presented at the 22nd European Hematology Association annual meeting in Madrid, Spain, from June 22-25, 2017.

"Research into blood cancers is at a pivotal point, where we're able to apply insights into the biology of disease to help evolve the treatment pathways, as well as continue to deepen our understanding of the disease in ways that have the potential to positively impact patients' lives," said Michael Pehl, President, Hematology and Oncology for Celgene. "The studies being shared this year illustrate our ongoing commitment to delivering innovative therapies to patients with serious and sometimes underserved blood cancers."

This year's data presented at EHA will support the role of Celgene therapies as the foundation of myeloma research, including data evaluating REVLIMID® (lenalidomide) across a variety of patient settings ranging from newly diagnosed to those receiving maintenance treatment following autologous hematopoietic stem cell transplant. The data also highlight the potential of Celgene treatments across a range of blood cancers such as lymphoma, MDS and beta-thalassemia. Findings from key Celgene research collaborations will also be presented, including updated data from the Phase I dose escalation and expansion study of IDHIFA® (enasidenib) in patients with relapsed/refractory acute myeloid leukemia and an isocitrate dehydrogenase-2 mutation.

Selected abstracts include:

Newly-Diagnosed Multiple Myeloma

Abstract #S102; Oral; Friday, June 23, 12:00 p.m., Hall A. Minimal Residual Disease (MRD) by Multiparameter Flow Cytometry (MFC) in Transplant Eligible Patients with Newly Diagnosed Multiple Myeloma (MM): Results from the EMN02/HO95 Phase 3 Trial (Oliva)

Abstract #S407; Oral; Saturday, June 24, 11:30 a.m., Hall A. Quadruplet vs. Sequential Triplet Induction Therapy for Multiple Myeloma Patients: Results of the MYELOMA XI Study (Pawlyn)

Abstract #S410; Oral; Saturday, June 24, 12:15 p.m., Hall A. Carfilzomib-Lenalidomide-Dexamethasone vs. Carfilzomib-Cyclophosphamide-Dexamethasone Induction: Planned Interim Analysis of the Randomized Forte Trial in Newly Diagnosed Multiple Myeloma (Gay)

Abstract #P349; Poster Discussion; Friday, June 23, 5:15 p.m., Hall 7. The Connect MM Registry: Impact of the Cytogenic Abnormality (11;14) on Survival Outcomes in African American and non-African American Patients with Newly Diagnosed Multiple Myeloma (Gasparetto)

Relapsed/Refractory Multiple Myeloma

Abstract #S142; Oral; Friday, June 23, 11:45 a.m., Room N109. First-in-Human Multicenter Study of BB2121 Anti-BCMA CAR T Cell Therapy for Relapsed/Refractory Multiple Myeloma: Updated Results (Lin)

Abstract #S456; Oral; Saturday, June 24, 4:00 p.m., Hall A. Phase 3 ELOQUENT-2 Study: Extended 4-Year Follow-up of Elotuzumab plus Lenalidomide/Dexamethasone vs. Lenalidomide/Dexamethasone in Relapsed/Refractory Multiple Myeloma

(Dimopoulos)

Abstract #P343; Poster Presentation; Friday, June 23, 5:15 p.m., Hall 7. MM-013 Phase 2 Multicenter Study of Pomalidomide (POM) plus Low-dose Dexamethasone (LODEX) in Patients (PTS) with Relapsed/Refractory Multiple Myeloma (RRMM) and Renal Impairment (RI) (Sonneveld)

Abstract #P680; Poster Presentation; Saturday, June 24, 5:30 p.m., Hall 7. Final Results of Phase (PH) 1/2 Study of Carfilzomib, Pomalidomide, and Dexamethasone (KPD) in Patients (PTS) with Relapsed/Refractory Multiple Myeloma (RRMM): A Multi-Center MMRC Study (Jakubowiak)

Maintenance in Multiple Myeloma

Abstract #S781; Oral; Sunday, June 25, 8:30 a.m., Hall D. Lenalidomide Induction and Maintenance Therapy for Transplant Eligible Myeloma Patients: Results of the MYELOMA XI Study (Pawlyn)

Abstract #P332; Poster Discussion; Friday, June 23, 5:15 p.m., Hall 7. Lenalidomide Maintenance vs. Placebo After Stem Cell Transplant for Patients with Multiple Myeloma: Overall Survival and Progression-free Survival After Adjusting for Treatment Crossover in CALGB (McCarthy)

Acute Myeloid Leukemia

Abstract #S471; Oral; Saturday, June 24, 4:00 p.m., Hall D. Enasidenib (AG-221) in Mutant-IDH2 Relapsed or Refractory Acute Myeloid Leukemia (R/R AML): Results of a Phase 1 Dose-escalation and Expansion Study (Stein)

Abstract #S791; Oral; Sunday, June 25, 8:30 a.m., Room N101. Molecular Predictors of Response to Azacitidine Therapy: The Results of the UK Trials Acceleration Programme RAVVA Study (Craddock)

Abstract #P208; Poster Discussion; Friday, June 23, 5:15 p.m., Hall 7. Stable Disease with Hematologic Improvement is Clinically Meaningful for Older Patients with Acute Myeloid Leukemia (AML) Treated with Azacitidine (Schuh)

Abstract #P215; Poster Discussion; Friday, June 23, 5:15 p.m., Hall 7. Differentiation Syndrome Associated with Enasidenib (AG-221), a Selective Inhibitor of Mutant Isocitrate Dehydrogenase 2 (MIDH2) (Fathi)

Abstract #P555; Poster Discussion; Saturday, June 24, 5:30 p.m., Hall 7. Response-adapted Azacitidine and Induction Chemotherapy in Patients > 60 Years Old with Newly Diagnosed AML Eligible for Chemotherapy: Results of the DRKS00004519 Study of the East German Study Group (Jaekel)

Lymphoma

Abstract #S467; Oral; Saturday, June 24, 4:15 p.m., Hall C. CC-122 in Combination with Obinutuzumab (GA101): Phase IB study in Relapsed or Refractory Patients with Diffuse Large B-cell Lymphoma, Follicular Lymphoma or Marginal Zone Lymphoma (Michot)

Abstract #P634; Poster Discussion; Saturday, June 24, 5:30 p.m., Hall 7. Phase IIIB Randomized Study of Lenalidomide plus Rituximab (R2) followed by Lenalidomide vs. Rituximab Maintenance in Patients with Relapsed/Refractory NHL: Analysis of Follicular Lymphoma Patients (Burke)

Myelodysplastic Syndromes

Abstract #P666; Poster Discussion; Saturday, June 24, 5:30 p.m., Hall 7. Luspatercept Increases Hemoglobin and Reduces Transfusion Burden in Patients with Lower-risk Myelodysplastic Syndromes (MDS): Long-term Results from Phase 2 PACE-MDS Study (Giagounidis)

Beta-Thalassemia

Abstract #S129; Oral; Friday, June 23, 11:45 a.m., Room N105. Luspatercept Increases Hemoglobin and Decreases Transfusion Burden in Adults with B-Thalassemia. (Piga)

The safety and efficacy of the agents and/or uses under investigation have not been established. There is no guarantee that the agents will receive health authority approval or become commercially available in any country for the uses being investigated.

A complete listing of abstracts can be found on the EHA Learning Center Web site at https://learningcenter.ehaweb.org/eha/.

About REVLIMID®

REVLIMID® (lenalidomide) in combination with dexamethasone (dex) is indicated for the treatment of patients with multiple myeloma (MM)

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

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

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

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

Allergic Reactions: REVLIMID is contraindicated in patients who have demonstrated 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 REVLIMID 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 REVLIMID

REVLIMID REMS® Program: See Boxed WARNINGS: Prescribers and pharmacies must be certified with the REVLIMID REMS program by enrolling and complying with the REMS requirements; pharmacies must only dispense to patients who are authorized to receive REVLIMID. 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: REVLIMID 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. **MM:** Patients taking REVLIMID/dex or REVLIMID maintenance therapy should have their complete blood counts (CBC) assessed every 7 days for the first 2 cycles, on days 1 and 15 of cycle 3, and every 28 days thereafter. **MDS:** 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 dose reduction. Please see the **Boxed WARNINGS** for further information. **MCL:** Patients taking REVLIMID for MCL should have their CBCs monitored weekly for the first cycle (28 days), every 2 weeks during cycles 2-4, and then monthly thereafter. Patients may require dose interruption and/or dose reduction

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 REVLIMID. 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 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 REVLIMID 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 REVLIMID arm. REVLIMID 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 REVLIMID, an increase of hematologic plus solid tumor SPM, notably AML and MDS, have been observed. Monitor patients for the development of SPM. Take into account both the potential benefit of REVLIMID and risk of SPM when considering treatment

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

Allergic Reactions: Angioedema and serious dermatologic reactions including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported. These events can be fatal. Patients with a prior history of Grade 4 rash associated with thalidomide treatment should not receive REVLIMID. REVLIMID interruption or discontinuation should be considered for Grade 2-3 skin rash. REVLIMID must be discontinued for angioedema, Grade 4 rash, exfoliative or bullous

rash, or if SJS or TEN is suspected and should not be resumed following discontinuation for these reactions. REVLIMID capsules contain lactose; risk-benefit of treatment should be evaluated in patients with lactose intolerance

Tumor Lysis Syndrome (TLS): Fatal instances of TLS have been reported during treatment with lenalidomide. The patients at risk of TLS are those with high tumor burden prior to treatment. These patients should be monitored closely and appropriate precautions taken

Tumor Flare Reaction (TFR): TFR has occurred during investigational use of lenalidomide for CLL and lymphoma. Monitoring and evaluation for TFR is recommended in patients with MCL. Tumor flare may mimic the progression of disease (PD). In patients with Grade 3 or 4 TFR, it is recommended to withhold treatment with REVLIMID until TFR resolves to ≤ Grade 1. REVLIMID 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 REVLIMID 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 start of REVLIMID treatment and during therapy

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 and 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 (46%), anemia (44%), neutropenia (35%), fatigue (33%), back pain (32%), asthenia (28%), insomnia (28%), rash (26%), decreased appetite (23%), cough (23%), dyspnea (22%), pyrexia (21%), abdominal pain (21%), 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 (5%, 47%), nasopharyngitis (2%, 35%), cough (10%, 27%), gastroenteritis (0%, 23%), diarrhea (55%, 39%), rash (32%, 8%), fatigue (23%, 11%), asthenia (0%, 30%), muscle spasm (0%, 33%), and pyrexia (8%, 21%)
- **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 (28% 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%)

DRUG INTERACTIONS

Periodic monitoring of digoxin plasma levels is recommended due to increased C_{max} 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 dex 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
- **PEDIATRIC USE:** Safety and effectiveness have not been established in pediatric patients
- **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.**

About POMALYST®

POMALYST® (pomalidomide) is a thalidomide analogue indicated, in combination with dexamethasone, for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor and have demonstrated disease progression on or within 60 days of completion of the last therapy.

Important Safety Information

WARNING: EMBRYO-FETAL TOXICITY and VENOUS AND ARTERIAL THROMBOEMBOLISM

Embryo-Fetal Toxicity

- **POMALYST is contraindicated in pregnancy. POMALYST is a thalidomide analogue. Thalidomide is a known human teratogen that causes severe birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting POMALYST treatment.**
- **Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after stopping POMALYST treatment.**

POMALYST is only available through a restricted distribution program called POMALYST REMS®.

Venous and Arterial Thromboembolism

- **Deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke occur in patients with multiple myeloma treated with POMALYST. Prophylactic antithrombotic measures were**

employed in clinical trials. Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.

CONTRAINDICATIONS: Pregnancy

- POMALYST can cause fetal harm and is contraindicated in females who are pregnant. If POMALYST is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity

- Females of Reproductive Potential: Must avoid pregnancy while taking POMALYST and for at least 4 weeks after completing therapy. Must commit either to abstain continuously from heterosexual sexual intercourse or to use 2 methods of reliable birth control, beginning 4 weeks prior to initiating treatment with POMALYST, during therapy, during dose interruptions, and continuing for 4 weeks following discontinuation of POMALYST therapy. Must obtain 2 negative pregnancy tests prior to initiating therapy
- Males: Pomalidomide 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 POMALYST and for up to 28 days after discontinuing POMALYST, even if they have undergone a successful vasectomy. Males must not donate sperm
- Blood Donation: Patients must not donate blood during treatment with POMALYST and for 1 month following discontinuation of POMALYST therapy because the blood might be given to a pregnant female patient whose fetus must not be exposed to POMALYST

POMALYST REMS® Program

Because of the embryo-fetal risk, POMALYST is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called "**POMALYST REMS®**." Prescribers and pharmacies must be certified with the program; patients must sign an agreement form and comply with the requirements. Further information about the **POMALYST REMS®** program is available at **www.CelgeneRiskManagement.com** or by telephone at 1-888-423-5436.

Venous and Arterial Thromboembolism: Venous thromboembolic events (DVT and PE) and arterial thromboembolic events (ATE) (myocardial infarction and stroke) have been observed in patients treated with POMALYST. In Trial 2, where anticoagulant therapies were mandated, thromboembolic events occurred in 8.0% of patients treated with POMALYST and low dose-dexamethasone (Low-dose Dex) vs 3.3% treated with high-dose dexamethasone. Venous thromboembolic events (VTE) occurred in 4.7% of patients treated with POMALYST and Low-dose Dex vs 1.3% treated with high-dose dexamethasone. Arterial thromboembolic events include terms for arterial thromboembolic events, ischemic cerebrovascular conditions, and ischemic heart disease. Arterial thromboembolic events occurred in 3.0% of patients treated with POMALYST and Low-dose Dex vs 1.3% treated with high-dose dexamethasone. 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).

Hematologic Toxicity: In trials 1 and 2 in patients who received POMALYST + Low-dose Dex, neutropenia (46%) was the most frequently reported Grade 3/4 adverse reaction, followed by anemia and thrombocytopenia. Monitor patients for hematologic toxicities, especially neutropenia. Monitor complete blood counts weekly for the first 8 weeks and monthly thereafter. Patients may require dose interruption and/or modification.

Hepatotoxicity: Hepatic failure, including fatal cases, has occurred in patients treated with POMALYST. Elevated levels of alanine aminotransferase and bilirubin have also been observed in patients treated with POMALYST. Monitor liver function tests monthly. Stop POMALYST upon elevation of liver enzymes. After return to baseline values, treatment at a lower dose may be considered.

Hypersensitivity Reactions: Angioedema and severe dermatologic reactions have been reported. Discontinue POMALYST for angioedema, skin exfoliation, bullae, or any other severe dermatologic reactions, and do not resume therapy.

Dizziness and Confusional State: In trials 1 and 2 in patients who received POMALYST + Low-dose Dex, 14% experienced dizziness and 7% a confusional state; 1% of patients experienced Grade 3 or 4 dizziness and 3% experienced a Grade 3 or 4 confusional state. Instruct patients to avoid situations where dizziness or confusional state may be a problem

and not to take other medications that may cause dizziness or confusional state without adequate medical advice.

Neuropathy: In trials 1 and 2, patients who received POMALYST + Low-dose Dex experienced neuropathy (18%) and peripheral neuropathy (~12%). In trial 2, 2% of patients experienced Grade 3 neuropathy.

Risk of Second Primary Malignancies: Cases of acute myelogenous leukemia have been reported in patients receiving POMALYST as an investigational therapy outside of multiple myeloma.

Tumor Lysis Syndrome: Tumor lysis syndrome (TLS) may occur in patients treated with POMALYST. Patients at risk are those with high tumor burden prior to treatment. These patients should be monitored closely and appropriate precautions taken.

ADVERSE REACTIONS

Nearly all patients treated with POMALYST + Low-dose Dex experienced at least one adverse reaction (99%). In trial 2, the most common adverse reactions included neutropenia (51.3%), fatigue and asthenia (46.7%), upper respiratory tract infection (31%), thrombocytopenia (29.7%), pyrexia (26.7%), dyspnea (25.3%), diarrhea (22%), constipation (21.7%), back pain (19.7%), cough (20%), pneumonia (19.3%), edema peripheral (17.3%), peripheral neuropathy (17.3%), bone pain (18%), nausea (15%), and muscle spasms (15.3%). Grade 3 or 4 adverse reactions included neutropenia (48.3%), thrombocytopenia (22%), and pneumonia (15.7%).

DRUG INTERACTIONS

Pomalidomide is primarily metabolized by CYP1A2 and CYP3A. Pomalidomide is also a substrate for P-glycoprotein (P-gp). Avoid the use of strong CYP1A2 inhibitors. If medically necessary to co-administer strong inhibitors of CYP1A2 in the presence of strong inhibitors of CYP3A4 and P-gp, reduce POMALYST dose by 50%. Cigarette smoking may reduce pomalidomide exposure due to CYP1A2 induction. Patients should be advised that smoking may reduce the efficacy of pomalidomide.

USE IN SPECIFIC POPULATIONS

Pregnancy: 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. Report any suspected fetal exposure to POMALYST to the FDA via the MedWatch program at 1-800-332-1088 and also to Celgene Corporation at 1-888-423-5436.

Nursing Mothers: It is not known if pomalidomide is excreted in human milk. Pomalidomide was excreted in the milk of lactating rats. Because many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants from POMALYST, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness of POMALYST in patients under the age of 18 have not been established.

Geriatric Use: No dosage adjustment is required for POMALYST based on age. Patients > 65 years of age were more likely than patients ≤65 years of age to experience pneumonia.

Renal and Hepatic Impairment: Pomalidomide is metabolized in the liver. Pomalidomide and its metabolites are primarily excreted by the kidneys. The influence of renal and hepatic impairment on the safety, efficacy, and pharmacokinetics of pomalidomide has not been evaluated. Avoid POMALYST in patients with a serum creatinine > 3.0 mg/dL. Avoid POMALYST in patients with serum bilirubin > 2.0 mg/dL and AST/ALT > 3.0 x ULN.

Please see full Prescribing Information, including Boxed WARNINGS.

About Celgene

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit www.celgene.com. Follow Celgene on social media: @Celgene, Pinterest, LinkedIn, Facebook and YouTube.

FORWARD-LOOKING STATEMENTS

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words "expects," "anticipates," "believes," "intends," "estimates," "plans," "will," "outlook" and similar expressions. Forward-looking statements are based on management's current plans, estimates, assumptions and projections, and speak only as of the date they are made. Celgene undertakes no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in Celgene's Annual Report on Form 10-K and other reports filed with the Securities and Exchange Commission.

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Source: Celgene Corporation