Celgene Announces Presentations of Investigational Studies in Blood Cancers at EHA 2016

**Continuing its commitment to meeting unmet needs in rare blood cancers, data presented at congress will help inform the future of patient care in hematology**

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced that more than 40 presentations reporting on investigational studies in blood cancers will be presented during the 21st European Hematology Association annual meeting in Copenhagen, Denmark, from June 9-12, 2016.

"At EHA this year, a significant number of studies will be presented across the range of blood cancers, demonstrating Celgene's commitment to develop therapies to meet the high unmet needs of patients living with diseases such as multiple myeloma, lymphomas, and myeloid diseases," said Michael Pehl, President, Hematology and Oncology for Celgene. "The data presented at scientific meetings like the EHA are the first opportunities to discuss and debate the evidence for various treatment pathways, and it will be exciting to see the progress being made across rare and sometimes underserved blood cancers, as well as the role the Celgene can continue to play in this space."

Investigational data to be presented include:

**Multiple Myeloma:**

- #S103 - A Meta-Analysis of Overall Survival in Patients with Multiple Myeloma Treated with Lenalidomide Maintenance After High-Dose Melphalan and Autologous Stem Cell Transplant - Oral - June 10, 12:15
- #S104 - Upfront or Salvage Transplant in Young Patients with Newly Diagnosed Multiple Myeloma: a Pooled Analysis of 529 Patients - Oral - June 10, 12:30 - Hall A1
- #E1316 - Revlimid, Bendamustine and Prednisolone (RBP) in Relapsed/Refractory Multiple Myeloma: Final Results of a Phase II Clinical Trial OSHO #077 - Poster - E-Poster Presentation
- #E1459 - Health Related Quality of Life in Multiple Myeloma Patients in Relation to Treatment Lines and Responses - Poster - E-Poster Presentation
- #E1300 - Updated Results of a Systematic Review of the Relative Effectiveness of Treatments in Relapsed / Refractory Multiple Myeloma - Poster - E-Poster Presentation
- #E1284 - Management of Adverse Events in Patients with Relapsed and Refractory Multiple Myeloma Treated with Pomalidomide Plus Low-Dose Dexamethasone: a Pooled Safety Analysis of 3 Clinical Trials - Poster - E-Poster Presentation
- #E1295 - A Pooled Analysis of Age on Outcomes in Patients With Refractory or Relapsed and Refractory Multiple Myeloma With Pomalidomide + Low-dose Dexamethasone - Poster - E-Poster Presentation
- #E1460 - Pomalidomide or Carfilzomib Use In Patients With Relapsed Multiple Myeloma: Real World Treatment Patterns, Time To Next Treatment and Economic Outcomes - Poster - E-Poster Presentation
- #P653 - Pomalidomide, Bortezomib, and Low-Dose Dexamethasone in Patients With Proteasome Inhibitor-Exposed and Lenalidomide-Refractory Myeloma: Results of A Multicenter, Dose-Escalation, Phase 1 Trial (MM-005) - Poster - June 11, 17:30, Hall H
- #PB1981 - The Stratus Trial (MM-010): Analysis of the Italian Subgroup of Patients with Relapsed/Refractory Multiple Myeloma Treated with Pomalidomide Plus Low-Dose Dexamethasone - ePub
- #PB1968 - A Phase 2 Multicenter Study of Pomalidomide in Combination With Low-Dose Dexamethasone in Patients With Relapsed and Refractory Multiple Myeloma in Japan: the MM-011 trial - ePub

**Lymphoma:**
Myeloid:

- **#S129** - CC-486 (Oral Azacitidine) in Patients with Myelodysplastic Syndromes (MDS) with Pretreatment Thrombocytopenia - Oral - June 10, 11.45, Hall C14
- **#S811** - Response-Adapted Sequential Azacitidine and Induction Chemotherapy in Patients > 60 Years Old with Newly Diagnosed AML Eligible for Chemotherapy (RAS-AZIC): Final Interim Analysis of the DRKS00004519 Study - Oral - June 12, 8.45, Hall C13
- **#S136** - RAP-536 (Murine ACE-536/Luspatercept) Inhibits Smad2/3 Signaling and Promotes Erythroid Differentiation by Restoring GATA-1 Function in Murine Model of β-thalassemia - Oral - June 10, 12.30, Hall C15
- **#S836** - Luspatercept (ACE-536) Decreases Transfusion Burden and Liver Iron Concentration in Regularly Transfused Adults with Beta-Thalassemia - Oral - June 10, 8.45, Room H6
- **#S131** - Luspatercept (ACE-536) Increases Hemoglobin and Reduces in Transfusion Burden in Patients with Low-Intermediate Risk Myelodysplastic Syndromes (MDS): Long-term Results from Phase 2 PACE-MDS Study - Oral - June 10, 12.15, Hall C14
- **#S809** - Outcome of Patients with refractory or Relapsed AML with IHD1 and IHD2 Mutations after Conventional Salvage Therapy: A Study of the German-Austrian AML study Group (AMLSG) - Oral - June 12, 8:15, Hall C13
- **#E1217** - Treatment-Emergent Adverse Events in Lenalidomide-Treated Low/Int-1-Risk Myelodysplastic Syndromes Patients Without Del(5q): Results From a Randomized Phase 3 Trial (MDS-005) - Poster, E-Poster Presentation
- **#P626** - Levels of Transfusion Burden and Associated Costs for Patients With Transfusion-Dependent Myelodysplastic Syndromes - Poster - June 11, 17.30, Hall H.
- **#E1211** - Cost Changes Associated With Achieving Transfusion Independence (TI) for Patients With Myelodysplastic Syndromes (MDS) - Poster, E-Poster Presentation
- **#P618** - Impact of Azacitidine Therapy on Overall Survival of Newly Diagnosed Patients With High-Risk Myelodysplastic Syndromes: a Post Hoc Analysis of the ERASME Study - Poster - June 11, 17.30, Hall H
- **#P252** - Clinical Benefit Among Lenalidomide-Treated Patients With RBC Transfusion-Dependent Low-/Int-1-Risk Myelodysplastic Syndromes Without Del(5q) - Poster - June 10, 17.45, Hall H
- **#P758** - Luspatercept (ACE-536) Increases Hemoglobin, Reduces Liver Iron Concentration, and Improves Quality of Life in Non-Transfusion Dependent Adults with Beta-Thalassemia - Poster - June 11, 17.30, Hall H
- **#P573** - Azacitidine (AZA) vs Conventional Care Regimens (CCR) in Patients With Acute Myeloid Leukemia (AML) with Myelodysplasia-Related Changes (MRC) per Central Review In AZA-AML-001 - Poster - June 11, 17.30, Hall H
- **#P576** - Hospitalization for Treatment-Emergent Adverse Events (TEAE) in Older (≥65 years) Patients with Acute Myeloid Leukemia (AML) with > 30% Bone Marrow (BM) Blasts in the Phase 3 AZA-AML-001 Study - Poster - June 11, 17.30, Hall H
- **#PB1917** - Serum Erythropoietin (sEPO) Testing and Treatment Patterns for Transfusion Dependent Patients With Myelodysplastic Syndromes (MDS) - ePub

Other presentations will report on data from investigational uses of Celgene approved therapies and pipeline candidates in blood cancers.

For a complete listing of abstracts, visit the [EHA web site](http://example.com).  

*All times Central European Time (CET)*
About REVLIMID®

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

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 (formerly known as the "RevAssist®" 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 hazard 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:

- REVLIMID is an analogue of thalidomide, a known human teratogen that causes life-threatening human birth defects or embryo-fetal death. An embryo-fetal development study in monkeys indicates that lenalidomide produced malformations in offspring of female monkeys who received drug during pregnancy, similar to birth defects observed in humans following exposure to thalidomide during pregnancy.

- **Females of Reproductive Potential:** Must avoid pregnancy for at least 4 weeks before beginning REVLIMID therapy, during therapy, during dose interruptions and for at least 4 weeks after completing therapy. Must commit either to abstain continuously from heterosexual sexual intercourse or to use two methods of reliable birth control beginning 4 weeks prior to initiating treatment with REVLIMID, during therapy, during dose interruptions and continuing for 4 weeks following discontinuation of REVLIMID. Must obtain 2 negative pregnancy tests prior to initiating therapy.

- **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 28 days 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 1 month 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

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

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 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. **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. For **MDS:** See Boxed WARNINGS.

Venous and Arterial Thromboembolism: Venous thromboembolic events (DVT and PE) and arterial thromboses are increased in patients treated with REVLIMID. A significantly increased risk of DVT (7.4%) and PE (3.7%) occurred in patients with MM after at least one prior therapy, treated with REVLIMID/dex compared to placebo/dex (3.1% and 0.9%) in clinical trials with varying use of anticoagulant therapies. In NDMM study, in which nearly all patients received antithrombotic prophylaxis, DVT (3.6%) and PE (3.8%) were reported in the Rd continuous arm. Myocardial infarction (MI, 1.7%) and stroke (CVA, 2.3%) are increased in patients with MM after at least 1 prior therapy who were treated with REVLIMID/dex therapy compared with placebo/dex (0.6%, and 0.9%) in clinical trials. In NDMM study, MI (including acute) was reported (2.3%) in the Rd Continuous arm. Frequency of serious adverse reactions of CVA was (0.8%) in the Rd Continuous arm. 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). In controlled clinical trials that did not use concomitant thromboprophylaxis, 21.5% overall thrombotic events occurred in patients with refractory and relapsed MM who were treated with REVLIMID/dex compared to 8.3% thrombosis in the placebo/dex group. Median time to first thrombosis event was 2.8 months. In NDMM study, which nearly all patients received antithrombotic prophylaxis, overall frequency of thrombotic events was 17.4% in combined Rd Continuous and Rd18 arms. Median time to first thrombosis event was 4.37 months. Thromboprophylaxis is recommended and regimen is based on patients underlying risks. ESAs and estrogens may further increase the risk of thrombosis and their use should be based on a benefit-risk decision. See Boxed WARNINGS.

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. In an interim analysis, there were 34 deaths among 210 patients on the REVLIMID treatment arm compared to 18 deaths among 211 patients in the chlorambucil treatment arm, and hazard ratio for overall survival was 1.92 [95% CI: 1.08-3.41] consistent with a 92% increase in risk of death. Serious adverse cardiovascular reactions, including atrial fibrillation, myocardial infarction, and...
Second Primary Malignancies: In clinical trials in patients with MM receiving REVLIMID, an increase of invasive second primary malignancies (SPM) notably AML and MDS have been observed. The increase of AML and MDS occurred predominantly in NDMM patients receiving REVLIMID in combination with oral melphalan (5.3%) or immediately following high dose intravenous melphalan and ASCT (up to 5.2%). The frequency of AML and MDS cases in the REVLIMID/dex arms was observed to be 0.4%. Cases of B-cell malignancies (including Hodgkin's Lymphomas) were observed in clinical trials where patients received REVLIMID in the post-ASCT setting. Patients who received REVLIMID-containing therapy until disease progression did not show a higher incidence of invasive SPM than patients treated in the fixed duration REVLIMID-containing arms. Monitor patients for the development of second primary malignancies. Take into account both the potential benefit of REVLIMID and risk of second primary malignancies when considering treatment.

Hepatotoxicity: Hepatic failure, including fatal cases, has occurred in patients treated with REVLIMID in combination with dex. The mechanism of drug-induced hepatotoxicity is unknown. 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 REVLIMID treatment should be evaluated in patients with lactose intolerance.

Tumor Lysis Syndrome: Fatal instances of tumor lysis syndrome (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: Tumor flare reaction (TFR) has occurred during investigational use of lenalidomide for CLL and lymphoma, and is characterized by tender lymph node swelling, low grade fever, pain and rash.

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 lenalidomide until TFR resolves to ≤ Grade 1. In the MCL trial, approximately 10% of subjects experienced TFR; all reports were Grade 1 or 2 in severity. All of the events occurred in cycle 1 and one patient developed TFR again in cycle 11. Lenalidomide may be continued in patients with Grade 1 and 2 TFR without interruption or modification, at the physician's discretion. Patients with Grade 1 or 2 TFR may also be treated with corticosteroids, non-steroidal anti-inflammatory drugs (NSAIDs) and/or narcotic analgesics for management of TFR symptoms. Patients with Grade 3 or 4 TFR may be treated for management of symptoms per the guidance for treatment of Grade 1 and 2 TFR.

Impaired Stem Cell Mobilization: A decrease in the number of CD34+ cells collected after treatment ( > 4 cycles) with REVLIMID has been reported. In patients who are autologous stem cell transplant (ASCT) candidates, referral to a transplant center should occur early in treatment to optimize timing of the stem cell collection.

ADVERSE REACTIONS

Multiple Myeloma

• In newly diagnosed patients the most frequently reported Grade 3 or 4 adverse reactions in Arm Rd Continuous included neutropenia (27.8%), anemia (18.2%), thrombocytopenia (8.3%), pneumonia (11.3%), asthenia (7.7%), fatigue (7.3%), back pain (7%), hypokalemia (6.6%), rash (7.3%), cataract (5.8%), dyspnea (5.6%), DVT (5.6%), hyperglycemia (5.3%), lymphopenia and leukopenia. The frequency of infections in Arm Rd Continuous was 75%

Adverse reactions reported in ≥20% of NDMM patients in Arm Rd Continuous: diarrhea (45.5%), anemia (43.8%), neutropenia (35%), fatigue (32.5%), back pain (32%), insomnia (27.6%), asthenia (28.2%), rash (26.1%), decreased appetite (23.1%), cough (22.7%), pyrexia (21.4%), muscle spasms (20.5%), and abdominal pain (20.5%). The frequency of onset of cataracts increased over time with 0.7% during the first 6 months and up to 9.6% by the second year of treatment with Arm Rd Continuous.

• After at least one prior therapy most adverse reactions and Grade 3 or 4 adverse reactions were more frequent in MM patients who received the combination of REVLIMID/dex compared to placebo/dex. Grade 3 or 4 adverse reactions included neutropenia 33.4% vs 3.4%, febrile neutropenia 2.3% vs 0%, DVT 8.2% vs 3.4% and PE 4% vs
Adverse reactions reported in ≥15% of MM patients (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%), weight decreased (20% vs 15%), nasopharyngitis (18% vs 9%), blurred vision (17% vs 11%), anorexia (16% vs 10%), and dysgeusia (15% vs 10%)

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%), and 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%)
- Serious adverse events reported in ≥2 patients treated with REVLIMID monotherapy for MCL included chronic obstructive pulmonary disease, clostridium difficile colitis, sepsis, basal cell carcinoma, and supraventricular tachycardia
- 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, in accordance with clinical judgment and based on standard clinical practice in patients receiving this medication, is recommended during administration of REVLIMID. It is not known whether there is an interaction between dex and warfarin. Close monitoring of PT and INR is recommended in MM patients taking concomitant warfarin. Erythropoietic agents, or other agents, that may increase the risk of thrombosis, such as estrogen containing therapies, should be used with caution after making a benefit-risk assessment in patients receiving REVLIMID

USE IN SPECIFIC POPULATIONS

Pregnancy: If pregnancy does occur during treatment, immediately discontinue the drug. Under these conditions, refer patient to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling. Any suspected fetal exposure to REVLIMID must be reported 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 whether REVLIMID is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother

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

Renal Impairment: Since REVLIMID is primarily excreted unchanged by the kidney, adjustments to the starting dose of REVLIMID are recommended to provide appropriate drug exposure in patients with moderate (CLcr 30-60 mL/min) or severe renal impairment (CLcr < 30 mL/min) and in patients on dialysis

Please see full Prescribing Information, including Boxed WARNINGS.
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 VIDAZA®

VIDAZA® (azacitidine for injection) is indicated for treatment of patients with the following French-American-British (FAB) myelodysplastic syndrome subtypes: refractory anemia (RA) or refractory anemia with ringed sideroblasts (RARS) (if accompanied by neutropenia or thrombocytopenia or requiring transfusions), refractory anemia with excess blasts (RAEB), refractory anemia with excess blasts in transformation (RAEB-T), and chronic myelomonocytic leukemia (CMMoL).

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS:

- VIDAZA is contraindicated in patients with a known hypersensitivity to azacitidine or mannitol and in patients with advanced malignant hepatic tumors

WARNINGS AND PRECAUTIONS:

Anemia, Neutropenia and Thrombocytopenia:

- Because treatment with VIDAZA causes anemia, neutropenia, and thrombocytopenia, monitor complete blood counts frequently for response and/or toxicity, at a minimum, prior to each dosing cycle

VIDAZA Toxicity in Patients with Severe Pre-existing Hepatic Impairment:

- Because azacitidine is potentially hepatotoxic in patients with severe preexisting hepatic impairment, caution is needed in patients with liver disease.

Renal Toxicity:

- Azacitidine and its metabolites are primarily excreted by the kidneys and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. These patients, including the elderly should be closely monitored for toxicity

Use in Pregnancy:

- VIDAZA may cause fetal harm when administered to a pregnant woman. Women of childbearing potential should be apprised of the potential hazard to the fetus. Men should be advised not to father a child while receiving VIDAZA

USE IN SPECIFIC POPULATIONS:

Nursing Mothers:

- Nursing mothers should be advised to discontinue nursing or the drug, taking into consideration the importance of the drug to the mother
ADVERSE REACTIONS:

- In Studies 1 and 2, the most commonly occurring adverse reactions by SC route were nausea (70.5%), anemia (69.5%), thrombocytopenia (65.5%), vomiting (54.1%), pyrexia (51.8%), leukopenia (48.2%), diarrhea (36.4%), injection site erythema (35.0%), constipation (33.6%), neutropenia (32.3%), and ecchymosis (30.5%). Other adverse reactions included dizziness (18.6%), chest pain (16.4%), febrile neutropenia (16.4%), myalgia (15.9%), injection site reaction (13.6%), and malaise (10.9%). In Study 3, the most common adverse reactions by IV route also included petechiae (45.8%), weakness (35.4%), rigors (35.4%), and hypokalemia (31.3%)

- In Study 4, the most commonly occurring adverse reactions were thrombocytopenia (69.7%), neutropenia (65.7%), anemia (51.4%), constipation (50.3%), nausea (48.0%), injection site erythema (42.9%), and pyrexia (30.3%). The most commonly occurring Grade 3/4 adverse reactions were neutropenia (61.1%), thrombocytopenia (58.3%), leukopenia (14.9%), anemia (13.7%), and febrile neutropenia (12.6%)

Please see full Prescribing Information

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 may contain 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. We undertake 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 our Annual Report on Form 10-K and other reports filed with the Securities and Exchange Commission.


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