Nearly 350 Abstracts Evaluating Celgene Therapies to Be Presented at American Society of Hematology Annual Meeting (ASH)

Presentations will focus on a wide range of disease areas including multiple myeloma, lymphoma, leukemia, myelodysplastic syndromes and beta-thalassemia

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced that data from nearly 350 abstracts, including more than 150 oral presentations, evaluating Celgene investigational agents and investigational uses of marketed products will be presented at the 58th American Society of Hematology Annual Meeting between Dec. 3-6 in San Diego, California.

Relevant presentations will include investigational data from Celgene agents in company-sponsored and investigator-initiated studies.

"Once again we look forward to an impactful collection of clinical and scientific data at ASH providing new insights into a broad range of hematologic malignancies," said Michael Pehl, President, Hematology and Oncology for Celgene. "The studies being shared this year underscore our continuing commitment to delivering innovative therapies to patients with serious blood cancers around the world."

Selected abstracts include*:

Multiple Myeloma

Clinical Data on Lenalidomide in Myeloma:

Abstract #241; Oral; Saturday, Dec. 3, 4 p.m., Seaport Ballroom ABCD (Manchester Grand Hyatt) Final Analysis of Overall Survival from the FIRST Trial (Facon)

Abstract #537; Oral; Sunday, Dec. 4, 5 p.m., Room 29 Health related Quality of Life in Patients with Newly Diagnosed Multiple Myeloma Receiving Any or Lenalidomide Maintenance after Autologous Stem Cell Transplant in the Connect MM Disease Registry (Abonour)

Abstract #673; Oral; Monday, Dec. 5, 7 a.m., Seaport Ballroom DE (Manchester Grand Hyatt) Intensification Therapy with Bortezomib-Melphalan-Prednisone Versus Autologous Stem Cell Transplantation for Newly Diagnosed Multiple Myeloma: An Intergroup, Multicenter, Phase III Study of the European Myeloma Network (EMN02/HO95 MM Trial) (Cavo)

Abstract #1143; Oral; Monday, Dec. 5, 5 p.m., Seaport Ballroom ABCD (Manchester Grand Hyatt) Lenalidomide is a Highly-Effective Maintenance Therapy in Myeloma Patients of All Ages; results of the Phase III Myeloma XI Study (Jackson)

Abstract #4497; Poster; Monday, Dec. 5, 6 p.m., Hall GH Pomalidomide + Low-Dose Dexamethasone Following Second-Line Lenalidomide-Based Therapy in Relapsed or Refractory Multiple Myeloma: A Phase 2 Study Investigating Efficacy and Safety (Siegel)

Clinical Data on Pomalidomide in Relapsed/Refractory Myeloma:

Abstract #2119; Poster; Saturday, Dec. 3, 5:30 p.m., Hall GH Pembrolizumab in Combination with Pomalidomide and Dexamethasone (PEMBRO/POM/DEX) for Pomalidomide Exposed Relapsed or Refractory Multiple Myeloma (Wilson)

Abstract #3316; Poster; Sunday, Dec. 4, 6 p.m., Hall GH A Phase I/II Trial of Ixazomib (Ix), Pomalidomide (POM) and Dexamethasone (DEX), in Relapsed/Refractory (R/R) Multiple Myeloma (MM) Patients; Responses in Double Refractory and High Risk Disease (Krishnan)
Abstract #3307; Poster; Sunday, Dec. 4, 6 p.m., Hall GH Selective HDAC6 Inhibitor ACY-241, an Oral Tablet, Combined with Pomalidomide and Dexamethasone: Safety and Efficacy of Escalation and Expansion Cohorts in Patients with Relapsed or Relapsed-and-Refractory Multiple Myeloma (ACE-MM-200 Study) (Niesvizky)

Abstract #1145; Oral; Monday, Dec. 5, 5:30 p.m., Seaport Ballroom BC (Manchester Grand Hyatt) A Multicenter, Open Label Phase I/II Study of Carfilzomib, Pomalidomide and Dexamethasone in Relapsed and/or Refractory Multiple Myeloma (MM) Patients (Bringhen)

Abstract #1151; Oral; Monday, Dec. 5, 5:30 p.m., Hall AB Efficacy of Daratumumab, Lenalidomide, and Dexamethasone Versus Lenalidomide and Dexamethasone in Relapsed or Refractory Multiple Myeloma Patients with 1 to 3 Prior Lines of Therapy: Updated Analysis of Pollux (Usmani)

Early Development Initiatives in Myeloma:

Abstract #1591; Poster; Saturday, Dec. 3, 5:30 p.m., Hall GH CC-220 is a Potent Cereblon Modulating Agent that Displays Anti-proliferative, Pro-Apoptotic and Immunomodulatory Activity on Sensitive and Resistant Multiple Myeloma Cell Lines (Bjorklund)

Abstract #1592; Poster; Saturday, Dec. 3, 5:30 p.m., Hall GH CC-122 is a Cereblon Modulating Agent that is Active in Lenalidomide-Resistant and Lenalidomide/Dexamethasone-Double-Resistant Multiple Myeloma Pre-clinical Models (Bjorklund)

Abstract #196; Oral; Saturday, Dec. 3, 2:45 p.m., Grand Hall D (Manchester Grand Hyatt) The Multiple Myeloma Genome Project: Development of a Molecular Segmentation Strategy for the Clinical Classification of Multiple Myeloma (Walker)

Lymphomas/CLL

Lenalidomide Maintenance Data:

Abstract #229; Oral; Saturday, Dec. 3, 4 p.m., Room 5AB Lenalidomide Maintenance after Front Line Therapy Substantially Prolongs Progression Free Survival in High Risk CLL: Interim Results of a Phase 3 Study (CLL M1 study of the German CLL Study Group) (Fink)

Abstract #230; Oral; Saturday, Dec. 3, 4:15 p.m., Room 5AB Results of the Phase III Study of Lenalidomide Versus Placebo as Maintenance Therapy Following Second-Line Treatment for Patients with B-Cell Chronic Lymphocytic Leukemia (the CONTINUUM Trial) (Foa)

Abstract #471; Oral; Sunday, Dec. 4, 5 p.m., Room 6B Final Analysis of an International Double-Blind randomized Phase III Study of Lenalidomide Maintenance in Elderly Patients with DLBCL Treated with R-CHOP in First Line, the REMARC Study from LYSA (Thieblemont)

Lenalidomide Combination Data:

Abstract #1798; Poster; Saturday, Dec. 3, 5:30 p.m., Hall GH MAGNIFY: Phase IIIb Randomized Study of Lenalidomide Plus Rituximab (R2) Followed by Lenalidomide vs. Rituximab Maintenance in Subjects with Relapsed/Refractory Follicular, Marginal Zone, or Mantle Cell Lymphoma (Andorsky)

Abstract #473; Oral; Sunday, Dec. 4, 5:30 p.m., Room 6B A Multicenter Open-Label Phase 1b/2 Study of Ibrutinib in Combination with Lenalidomide and Rituximab in Patients with Relapsed or Refractory Diffuse Large B-Cell Lymphoma (DLBCL) (Goy)

Abstract #1099; Oral; Monday, Dec. 5, 4:30 p.m., Ballroom 20A Rituximab Plus Lenalidomide Versus Rituximab Monotherapy in Untreated Follicular Lymphoma Patients in Need of Therapy. First Analysis of Survival Endpoints of the Randomized Phase II Trial SAKK 35/10 (Kimby)

Abstract #4199; Poster; Monday, Dec. 5, 6 p.m., Hall GH A Phase 1B Study of CC 122 in Combination with Obinutuzumab (GA101) in Relapsed or Refractory Diffuse Large B-Cell Lymphoma and Indolent Non-Hodgkin Lymphoma (Michot)

Lenalidomide Data in Mantle Cell Lymphoma:

Abstract #1786; Poster; Saturday, Dec. 3, 5:30 p.m., Hall GH Effectiveness of Lenalidomide in Mantle Cell Lymphoma Patients who Relapsed/Progressed After or were Refractory/Intolerant to Ibrutinib: The MCL-004 Study (Wang)
Abstract #4188; Poster; Monday, Dec. 5, 6 p.m., Hall GH CC-122 Exhibits Greater Preclinical Activity in Mantle Cell Lymphoma Than Lenalidomide Through A Combination of Direct Cell-autonomous and Increased Antibody Dependent Cell-mediated Cytotoxicity (Hagner)

Surrogate Outcomes Data:

Abstract #3027; Poster; Sunday, Dec. 4, 6 p.m., Hall GH Utility of Progression-Free Survival at 24 months (PFS24) to Predict Subsequent Outcome for Patients with Diffuse Large B-cell Lymphoma (DLBCL) Enrolled on Randomized Clinical Trials: Findings from a Surrogate Endpoint in Aggressive Lymphoma (SEAL) Analysis of Individual Patient Data (Maurer)

Abstract #1102; Oral; Monday, Dec. 5, 5:15 p.m., Ballroom 20A Outcomes for Elderly Patients with Follicular Lymphoma (FL) Using Individual Patient Data (IPD) from 5922 Patients in 18 Randomized Controlled Trials (RCTs): A FL Analysis of Surrogate Hypothesis (FLASH) Group Study (Flowers)

Abstract #4196; Poster; Monday, Dec. 5, 6 p.m., Hall GH Evaluation of Progression-free Survival (PFS) as a Surrogate Endpoint for Overall Survival (OS) in First-Line Therapy for Diffuse Large B-Cell Lymphoma (DLBCL): Findings from the Surrogate Endpoint in Aggressive Lymphoma (SEAL) Analysis of Individual Patient Data from 7507 Patients (Shi)

MDS/AML/Beta-Thalassemia

Emerging Clinical Data from Investigational cc486, ag221 (enasidenib) and Luspatercept Studies:

Abstract #905; Oral; Monday, Dec. 5, 3:45 p.m., San Diego Ballroom AB (Marriott Marquis San Diego Marina) CC-486 (Oral Azacitidine) in Patients with Hematological Malignancies Who Had Received Prior Treatment with Injectable Hypomethylating Agents (HMAs): Results from Phase 1/2 CC-486 Studies (Garcia-Manero)

Abstract #343; Oral; Sunday, Dec. 4, 9:30 a.m., Grand Hall C (Manchester Grand Hyatt) Enasidenib (AG-221), a Potent Oral Inhibitor of Mutant Isocitrate Dehydrogenase 2 (IDH2) Enzyme, Induces Hematologic Responses in Patients with Myelodysplastic Syndromes (MDS) (Stein)

Abstract #851; Oral; Monday, Dec. 5, 3:45 p.m., Room 7 AB Luspatercept Increases Hemoglobin, Decreases Transfusion Burden and Improves Iron Overload in Adults with Beta-Thalassemia (Piga)

Abstract #3168; Poster; Sunday, Dec. 4, 6 p.m., Hall GH Luspatercept Increases Hemoglobin and Reduces Transfusion Burden in Patients with Low-Intermediate Risk Myelodysplastic Syndromes (MDS): Long-Term results from Phase II PACE-MDS Study (Platzbecker)

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 ASH Web site at http://www.hematology.org/Annual-Meeting/Abstracts/

*All times Pacific Standard Time

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: 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 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: 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 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 Black Box 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 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

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 invasive SPM notably AML and MDS have been observed. Monitor patients for the development of SPMs. Take into account both the potential benefit of REVLIMID and risk of SPMs 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 of 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

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%)

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 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 dex and warfarin. Close monitoring of PT and INR is recommended in MM patients taking concomitant warfarin.

**NURSING MOTHERS**

Discontinue drug or nursing taking into consideration the importance of the drug to the mother

**PEDIATRIC USE**

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

**RENAIL IMPAIRMENT**

REVLIMID is primarily excreted unchanged by the kidneys; adjustments to the starting dose are recommended to provide appropriate drug exposure in patients with moderate or severe renal impairment and in patients on dialysis.

Please see full Prescribing Information, including Boxed WARNINGS.

**About POMALYST/IMNOVID**

**Indication**
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 risk to a fetus.

WARNINGS AND PRECAUTIONS

- Embryo-Fetal Toxicity & Females of Reproductive Potential: See Boxed WARNINGS
  - 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 4 weeks 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: See Boxed WARNINGS
  - Prescribers and pharmacies must be certified with the POMALYST REMS program by enrolling and complying with the REMS requirements; pharmacies must only dispense to patients who are authorized to receive POMALYST. 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.
  - 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: See Boxed WARNINGS. 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 choice of regimen should be based on assessment of the patient's underlying risk factors.

- Hematologic Toxicity: Neutropenia (46%) was the most frequently reported Grade 3/4 adverse reaction in patients taking POMALYST in clinical trials, followed by anemia and thrombocytopenia. 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 patients taking POMALYST in clinical trials, 14% experienced dizziness (1% Grade 3 or 4) and 7% a confusional state (3% Grade 3 or 4). 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 patients taking POMALYST in clinical trials, 18% experienced neuropathy (2% Grade 3 in one trial) and 12% peripheral neuropathy.

**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 (TLS):** 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%). 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%), bone pain (18%), edema peripheral (17.3%), peripheral neuropathy (17.3%), muscle spasms (15.3%), and nausea (15%). Grade 3 or 4 adverse reactions included neutropenia (48.3%), thrombocytopenia (22%), and pneumonia (15.7%).

**DRUG INTERACTIONS**

Avoid concomitant use of POMALYST with strong inhibitors of CYP1A2. Consider alternative treatments. If a strong CYP1A2 inhibitor must be used, reduce POMALYST dose by 50%.

**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 POMALYST pregnancy exposure registry that monitors pregnancy outcomes in females exposed to POMALYST during pregnancy as well as female partners of male patients who are exposed to POMALYST. This registry is also used to understand the root cause for the pregnancy. Report any suspected fetal exposure to POMALYST 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 pomalidomide in human milk, the effects of POMALYST on the breastfed infant, or the effects of POMALYST on milk production. 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 breastfed infants from POMALYST, advise a nursing woman to discontinue breastfeeding during treatment with POMALYST.

**Pediatric Use:** Safety and effectiveness have not been established in pediatric patients.

**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 Impairment:** Reduce POMALYST dose by 25% in patients with severe renal impairment requiring dialysis. Take dose of POMALYST following hemodialysis on hemodialysis days.

**Hepatic Impairment:** Reduce POMALYST dose by 25% in patients with mild to moderate hepatic impairment and 50% in patients with severe hepatic impairment.

**Smoking Tobacco:** Advise patients that smoking may reduce the efficacy of POMALYST. Cigarette smoking reduces the AUC of pomalidomide by 32% by CYP1A2 induction.

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. 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 our other reports filed with the Securities and Exchange Commission.


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