Results from More Than 100 Abstracts Highlighting Celgene Pipeline Compounds and Therapies to Be Presented at the American Society of Hematology Annual Meeting (ASH)

Presentations will cover a wide range of blood diseases including multiple myeloma, lymphoma, chronic lymphocytic leukemia, acute myeloid leukemia, myelodysplastic syndromes and beta-thalassemia

First data read-out of pivotal Phase 3 MEDALIST trial in patients with myelodysplastic syndrome (MDS) to be highlighted during the ASH Plenary Session

SUMMIT, N.J.-- (November 1, 2018) -- Celgene Corporation (NASDAQ:CELG) today announced that data from more than 100 abstracts, including a study being featured as a plenary presentation and more than 40 selected for oral presentations, evaluating Celgene investigational agents and investigational uses of marketed products will be presented at the 60th American Society of Hematology Annual Meeting between Dec. 1-4 in San Diego, CA.

"Celgene is deeply committed to furthering our understanding of blood cancers and encouraged by the promise of new innovations to improve or extend the lives of patients living with these intractable diseases," said Dr. Alise Reicin, President, Global Clinical Development for Celgene. "Importantly, this year's ASH data highlight the advancement of Celgene's pipeline including first-in-class compounds with the potential to transform treatment across multiple blood cancers."

Presentations will include data from Celgene investigational agents in company-sponsored or investigator-initiated clinical studies across the company's approved and investigational portfolio. Abstracts highlight some of the first results of key pivotal data for the company's pipeline assets, illustrating the breadth and potential of the hematology portfolio. Of note, a first look at the results from the MEDALIST trial in patients with myelodysplastic syndrome (MDS) will be presented during the Plenary Scientific Session, which honors the top six research papers submitted for presentation at the meeting. Experts will also share results from key approved therapies and investigational CAR T cell therapies in non-Hodgkin's lymphoma, chronic lymphocytic leukemia, beta thalassemia and multiple myeloma.

Key presentations include:

- First data of the pivotal, Phase 3, MEDALIST trial featured in the Plenary Scientific Sessions, highlighting the potential of luspatercept to address a significant unmet need in patients with MDS;
- First data of the pivotal, Phase 3, BELIEVE trial highlighting the potential for luspatercept to address a significant unmet need in adult patients with beta thalassemia;
- Data from the phase 1/2 TRANSCEND CLL-004 trial evaluating liso-cel (JCAR017) in patients with relapsed and/or refractory chronic lymphocytic leukemia (CLL);
- Initial results from a phase 1 trial of bb21217, a next-generation anti-BCMA CAR T therapy, in patients with relapsed and/or refractory multiple myeloma (RRMM);
- Data from the phase 1/2 EVOLVE trial evaluating JCARH125 in patients with RRMM; and
- First data from the Phase 3, AUGMENT trial, a chemotherapy-free regimen of REVLIMID® plus rituximab (R²) in patients with relapsed and/or refractory indolent non-Hodgkin’s lymphoma.

Selected abstracts include*:
Plenary Session

Abstract #1; Plenary; Sunday, Dec. 2, 2:00 p.m., Hall AB, The MEDALIST Trial: Results of a Phase 3, Randomized, Double-Blind, Placebo-Controlled, Randomized Study of Luspatercept to Treat Anemia in Patients with Very Low-, Low-, or Intermediate-Risk Myelodysplastic Syndromes (MDS) with Ring Sideroblasts (RS) Who Require Red Blood Cell (RBC) Transfusions (List)

Beta Thalassemia

Abstract #163; Oral; Saturday, Dec. 1, 2:00 p.m., Room 30D, The BELIEVE Trial: Results of a Phase 3, Randomized, Double-Blind, Placebo-Controlled, Study of Luspatercept in Adult Beta-Thalassemia Patients Who Require Regular Red Blood Cell (RBC) Transfusions (Cappellini)

Myeloid Diseases

New data findings evaluate Celgene in-line and investigational therapies in myeloid diseases.

Abstract #835; Oral; Monday, Dec.3, 2:45 p.m., Room 25B, Real-World Treatment Patterns and Comparative Effectiveness Among a Population of Elderly Patients with Acute Myeloid Leukemia (AML) (Medeiros)

Abstract #4731; Poster; Monday, Dec. 3, 6:00 p.m., Hall GH, Factors Associated with Early Therapy Initiation in Patients (Pts) with Myelodysplastic Syndromes (MDS) in the Connect® MDS/AML Disease Registry (Cogle)

Chimeric Antigen Receptor T-cell therapy (CAR T)

New data highlight growing base of research in cellular immunotherapy across multiple blood cancers.

Abstract #319; Oral; Sunday, Dec. 2, 7:30 a.m., Room 25B, Estimation of the Resource Utilization and Costs of Cytokine Release Syndrome Observed in the TRANSCEND-NHL Clinical Trial: A Micro-Costing Study (Siddiqi)

Abstract #300; Oral; Sunday, Dec. 2, 8:45 a.m., Marriott Marquis San Diego Marina, Pacific Ballroom 20, Rapid MRD-negative Responses in Patients with Relapsed/Refractory CLL Treated with Liso-cel, a CD-19-directed CAR T-cell Product: Preliminary Results from TRANSCEND CLL 004, a Phase 1/2 Study Including Patients with High-Risk Disease Previously Treated with ibrutinib (Siddiqi)

Abstract #488; Oral; Sunday, Dec. 2, 4:45 p.m., Room 6B, Initial results from a phase 1 clinical study of bb21217, a next-generation anti-BCMA CAR T therapy (Shah)

Abstract #957; Oral; Monday, Dec. 3, 5:00 p.m., Ballroom 20A, JCARRH125, Anti-BCMA CAR T-cell Therapy for Relapsed/Refractory Multiple Myeloma: Initial Proof of Concept Results from a Phase 1/2 Multicenter Study (EVOLVE) (Mailankody)

Lymphoma/Chronic Lymphocytic Leukemia (CLL)

Multiple studies evaluate novel chemotherapy-free combinations in lymphoma and chronic lymphocytic leukemia.

Abstract #445; Oral; Sunday, Dec. 2, 4:30 p.m., Hall AB, AUGMENT: A Phase III Randomized Study of Lenalidomide Plus Rituximab (R²) vs. Rituximab/Placebo in Patients with Relapsed/Refractory Indolent Non-Hodgkin’s Lymphoma (Leonard)

Abstract #446; Oral; Sunday, Dec. 2, 4:45 p.m., Hall AB, A Phase II LYSA Study of Obinutuzumab Combined with Lenalidomide for Advanced Front-Line Follicular B-Cell Lymphoma in Need of Systemic Therapy (Morschhauser)

Abstract #999; Oral; Monday, Dec. 3, 6:45 p.m., Room 6F, Lenalidomide in Combination with CHOP in Patients with Angioimmunoblastic T Cell Lymphoma (AITL): Final Analysis of Clinical and Molecular Data of a
Phase 2 LYSA Study (Lemonnier)

Multiple Myeloma

New multiple myeloma data reinforces IMiD® therapies as a foundation of myeloma research.

Abstract #112; Oral; Saturday, Dec 1, 10:15 a.m., Marriott Marquis San Diego Marina, Grand Ballroom 7, Clinical Significance and Transcriptional Profiling of Persistent Minimal Residual Disease (MRD) in Multiple Myeloma (MM) Patients With Standard-Risk (SR) and High-Risk (HR) Cytogenetics (Goicoechea)

Abstract #243; Oral; Saturday, Dec. 1, 4:30 p.m., Marriott Marquis San Diego Marina, Grand Ballroom 7, Deep immunoprofiling of the bone marrow microenvironment changes underlying the multistep progression of multiple myeloma (Young)

Abstract #121; Oral; Sunday, Dec 2, 8:30 a.m., Marriott Marquis San Diego Marina, Grand Ballroom 7, Efficacy and Feasibility of Dose/Schedule-Adjusted Rd-R vs. Continuous Rd in Elderly and Intermediate-Fit Newly Diagnosed Multiple Myeloma (NDMM) Patients: RV-MM-PI-0752 Phase III Randomized Study (Larocca)

Abstract #474; Oral; Sunday, Dec 2, 5:45 p.m., Marriott Marquis San Diego Marina, Grand Ballroom 7, Immunofixation (IF) in Urine is Really Necessary to Define Complete Remission in Multiple Myeloma (MM): A Subanalysis from the PETHEMA/GEM2012MENOS65 Phase III Clinical Trial (Ubieto)

Abstract #716; Oral; Monday, Dec. 3, 10:45 a.m., Room 25B, The Impact of Lenalidomide, Bortezomib, and Dexamethasone Treatment on Health-Related Quality of Life in Transplant-Eligible Patients with Newly-Diagnosed Multiple Myeloma: Results from the IFM/DFCI 2009 Trial (Roussel)

Abstract #1960; Poster; Saturday, Dec. 1, 6:00 p.m., Hall GH, Health-Related Quality of Life among Patients with Relapsed or Refractory Multiple Myeloma who Received Pomalidomide, Bortezomib, and Low-Dose Dexamethasone Versus Bortezomib and Low-Dose Dexamethasone – Results from the Phase 3 OPTIMISMM Study (Weisel)

Abstract #2012; Poster; Saturday, Dec. 1, 6:15 p.m., Hall GH, Immune Profiling of Relapsed or Refractory Multiple Myeloma Patients Treated With Pomalidomide and Low-Dose Dexamethasone in Combination With Daratumumab (Pierceall)

Abstract #2243; Poster; Saturday, Dec. 1, 6:15 p.m., Hall GH, Real-World Outcomes for Transplant-Ineligible Patients With Newly Diagnosed Multiple Myeloma (NDMM) Treated With Lenalidomide, Bortezomib, and Dexamethasone (RVD) or Vd: An Enhanced Electronic Health Records (EHR) Database Analysis (Chari)

Abstract #3271; Poster; Sunday, Dec. 2, 6:00 p.m., Hall GH, Pomalidomide + Low-Dose Dexamethasone + Daratumumab in Relapsed and/or Refractory Multiple Myeloma after Lenalidomide-Based Treatment Failure (Siegel)

Abstract #3278; Poster; Sunday, Dec. 2, 6:00 p.m., Hall GH, Pomalidomide + Bortezomib + Low-Dose Dexamethasone vs Bortezomib + Low-Dose Dexamethasone as Second-Line Treatment in Patients with Lenalidomide-Pretreated Multiple Myeloma: A Subgroup Analysis of the Phase 3 OPTIMISMM Trial (Dimopoulos)

Abstract #3445; Poster; Sunday, Dec. 2, 6:00 p.m., Hall GH, The Impact of RVD or VCD Induction on Response 3 Months after First Line Autologous Transplant in Multiple Myeloma. A single-center Retrospective Analysis (Moksnes)

Abstract #3232; Poster; Sunday, Dec. 2, 6:00 p.m., Hall GH, Treatment Choices and Outcomes for Patients with Multiple Myeloma (MM) After Relapse on Lenalidomide (LEN) Maintenance Therapy (mt): Results from the Connect® MM Registry (Jagannath)

Abstract # 3245; Poster; Sunday, Dec. 2, 6:00 p.m., Hall GH, Integrated Analysis of Randomized Controlled
Trials Evaluating Bortezomib + Lenalidomide + Dexamethasone or Bortezomib + Thalidomide +
Dexamethasone Induction in Transplant-Eligible Newly Diagnosed Multiple Myeloma (Rosinol)

Abstract #4744; Poster; Monday, Dec. 3, 6:00 p.m., Hall GH, Relative Efficacy of Treatment Options in Newly
Diagnosed Multiple Myeloma (NDMM): Results from a Systematic Literature Review (SLR) and Network
Meta-Analysis (NMA) (Ramasamy)

Abstract #4737; Poster; Monday, Dec. 3, 6:00 p.m., Hall GH, Survival Analysis from the CALGB Study of
Lenalidomide Maintenance Therapy in Newly Diagnosed Multiple Myeloma Post-Autologous Stem Cell
Transplantation Adjusted for Crossover (McCarthy)

The safety and efficacy of investigational agents and/or investigational uses of approved marketed products 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 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

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

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity: See Boxed WARNINGS
• Females of Reproductive Potential: See Boxed WARNINGS
• Males: Lenalidomide is present in the semen of patients receiving the drug. Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking REVLIMID and for up to 4 weeks after discontinuing REVLIMID, even if they have undergone a successful vasectomy. Male patients taking REVLIMID must not donate sperm
• Blood Donation: Patients must not donate blood during treatment with 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 as 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 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 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

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

Hepatotoxicity: Hepatic failure, including fatal cases, has occurred in patients treated with 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

Severe Cutaneous Reactions Including Hypersensitivity Reactions: Angioedema and severe cutaneous reactions including Stevens-Johnson syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported. DRESS may present with a cutaneous reaction (such as rash, or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. 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, TEN, or DRESS is suspected and should not be resumed following discontinuation for these reactions

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

Early Mortality in Patients with MCL: In another MCL study, there was an increase in early deaths (within 20 weeks), 12.9% in the REVLIMID arm versus 7.1% in the control arm. Risk factors for early deaths include high tumor burden, MIPI score at diagnosis, and high WBC at baseline (≥10 x 10^9/L)

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%), 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%)

- 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 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 in patients on dialysis.

Please see full Prescribing Information, including Boxed WARNINGS.

About POMALYST/IMNOVID

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 4 weeks 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.
- **Increased Mortality with Pembrolizumab**: In clinical trials in patients with multiple myeloma, the addition of pembrolizumab to a thalidomide analogue plus dexamethasone resulted in increased mortality. Treatment of patients with multiple myeloma with a PD-1 or PD-L1 blocking antibody in combination with a thalidomide analogue plus dexamethasone is not recommended outside of controlled clinical trials.
- **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.
- **Severe Cutaneous Reactions Including Hypersensitivity Reactions**: Angioedema and severe cutaneous reactions including Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported. DRESS may present with a cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, fever, and/or lymphadenopathy with systemic complications such as hepatitis, nephritis, pneumonitis, myocarditis, and/or pericarditis. Discontinue POMALYST for angioedema, skin exfoliation, bullae, or any other severe cutaneous reactions such as SJS, TEN or DRESS, 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**

The most common adverse reactions for POMALYST (≥30%) included fatigue and asthenia, neutropenia, anemia, constipation, nausea, diarrhea, dyspnea, upper-respiratory tract infections, back pain, and pyrexia.

In the phase III trial, nearly all patients treated with POMALYST + low-dose dex experienced at least one adverse reaction (99%). Adverse reactions (≥15% in the POMALYST + low-dose dex arm and ≥2% higher than control) 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 (≥15% in the POMALYST + low-dose dex arm and ≥1% higher than control) 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 child, 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 a breastfed child from POMALYST, advise women not to breastfeed 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 IDHIFA**

IDHIFA (enasidenib) is indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase-2 mutation as detected by an FDA-approved test.

**Important Safety Information**

**WARNING: DIFFERENTIATION SYNDROME**
Patients treated with IDHIFA have experienced symptoms of differentiation syndrome, which can be fatal if not treated. Symptoms may include fever, dyspnea, acute respiratory distress, pulmonary infiltrates, pleural or pericardial effusions, rapid weight gain or peripheral edema, lymphadenopathy, bone pain, and hepatic, renal, or multi-organ dysfunction. If differentiation syndrome is suspected, initiate corticosteroid therapy and hemodynamic monitoring until symptom resolution.

**WARNINGS AND PRECAUTIONS**

**Differentiation Syndrome:** See Boxed WARNING. In the clinical trial, 14% of patients treated with IDHIFA experienced differentiation syndrome, which may be life-threatening or fatal if not treated. Differentiation syndrome has been observed with and without concomitant hyperleukocytosis, as early as 10 days and at up to 5 months after IDHIFA initiation. Symptoms in patients treated with IDHIFA included acute respiratory distress represented by dyspnea and/or hypoxia and need for supplemental oxygen; pulmonary infiltrates and pleural effusion; renal impairment; fever; lymphadenopathy; bone pain; peripheral edema with rapid weight gain; and pericardial effusion. Hepatic, renal, and multi-organ dysfunction have also been observed. If differentiation syndrome is suspected, initiate systemic corticosteroids and hemodynamic monitoring until improvement. Taper corticosteroids only after
resolution of symptoms. Differentiation syndrome symptoms may recur with premature discontinuation of corticosteroids. If severe pulmonary symptoms requiring intubation or ventilator support and/or renal dysfunction persist for more than 48 hours after initiation of corticosteroids, interrupt IDHIFA until signs and symptoms are no longer severe. Hospitalization for close observation and monitoring of patients with pulmonary and/or renal manifestation is recommended.

Embryo-Fetal Toxicity: Based on animal embryo-fetal toxicity studies, IDHIFA can cause embryo-fetal harm when administered to a pregnant woman. Advise females of reproductive potential and males with female partners of reproductive potential to use effective contraception during treatment with IDHIFA and for at least 1 month after the last dose. Pregnant women, patients becoming pregnant while receiving IDHIFA, or male patients with pregnant female partners should be apprised of the potential risk to the fetus.

ADVERSE REACTIONS

• The most common adverse reactions (≥20%) included total bilirubin increased (81%), calcium decreased (74%), nausea (50%), diarrhea (43%), potassium decreased (41%), vomiting (34%), decreased appetite (34%), and phosphorus decreased (27%)

• The most frequently reported ≥Grade 3 adverse reactions (≥5%) included total bilirubin increased (15%), potassium decreased (15%), phosphorus decreased (8%), calcium decreased (8%), diarrhea (8%), differentiation syndrome (7%), non-infectious leukocytosis (6%), tumor lysis syndrome (6%), and nausea (5%)

• Serious adverse reactions were reported in 77.1% of patients. The most frequent serious adverse reactions (≥2%) were leukocytosis (10%), diarrhea (6%), nausea (5%), vomiting (3%), decreased appetite (3%), tumor lysis syndrome (5%), and differentiation syndrome (8%). Differentiation syndrome events characterized as serious included pyrexia, renal failure acute, hypoxia, respiratory failure, and multi-organ failure

LACTATION

Many drugs are excreted in human milk and because of the potential for adverse reactions in breastfed infants, advise women not to breastfeed during treatment with IDHIFA and for at least 1 month after the last dose.

Please see full Prescribing Information, including Boxed WARNING

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.

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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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