Celgene Announces Presentations of Investigational Studies in Solid Tumor and Blood Cancers at ASCO 2016

SUMMIT, N.J.--(BUSINESS WIRE)-- Celgene Corporation (NASDAQ:CELG) today announced more than 65 presentations reporting on investigational studies in blood and solid tumor cancers will be presented during the 52nd American Society of Clinical Oncology meeting in Chicago, Ill. from June 3-7, 2016.

"At ASCO this year, we look forward to a wide range of data demonstrating the increasing potential of Celgene therapies in hard-to-treat cancers," said Michael Pehl, President, Hematology and Oncology for Celgene. "These studies are helping to advance the understanding of our therapies as backbones of potentially powerful new combinations in diseases like multiple myeloma and pancreatic cancer."

Investigational data include:

**Multiple Myeloma:**

- #8001 Lenalidomide (LEN) maintenance (MNTC) after high-dose melphalan and autologous stem cell transplant (ASCT) in multiple myeloma (MM): A meta-analysis (MA) of overall survival (OS) - Oral - 3:12 p.m., Friday, June 3, E354b
- #8007 Phase 1/2 study of carfilzomib, pomalidomide, and dexamethasone (KPd) in Pts with RRMM: A Multiple Myeloma Research Consortium multicenter study - Oral - 5:12 p.m., Friday, June 3, Room E354b
- #8008 A phase I/II study of ixazomib (Ix) pomalidomide (POM) dexamethasone (DEX) in RRMM: Initial results - Oral - 5:24 p.m., Friday, June 3, Room E354b
- #8009 A phase Ib dose escalation trial of isatuximab (SAR650984, anti-CD38 mAb) plus Lenalidomide/Dexamethasone in RRMM: Interim results from two new dose cohorts - Oral - 9:45 a.m., Tuesday, June 7, E354b
- #8010 Pembrolizumab in combination with Len and low-dose Dex for RRMM: Final efficacy and safety analysis - Oral - 10:09 a.m., Tuesday, June 7, E354b
- #8018 Efficacy and safety of ixazomib plus lenalidomide-dexamethasone (IRd) vs placebo-Rd in patients with RRMM by cytogenetic risk status in the global phase III Tourmaline-MM1 study - Poster discussion - 3 p.m., Monday, June 6, E354b
- #8021 Economic evaluation of carfilzomib + lenalidomide + dexamethasone (KRd) vs lenalidomide + dexamethasone (Rd) in RRMM - Poster discussion - 3 p.m., Monday, June 6, E354b
- #8031 Adverse event (AE) management in pts with RRMM taking POM plus LoDEX: A pooled analysis from 3 clinical trials - Poster - 8 a.m., Monday, June 6, Hall A
- #8038 Real world health and economic outcomes in patients with NSCT multiple myeloma initially treated with lenalidomide and/or bortezomib-based regimens - Poster - 8 a.m., Monday, June 6, Hall A
- #8042 Real world treatment patterns, time to next treatment and economic outcomes in relapsed multiple myeloma patients treated with pomalidomide or carfilzomib - Poster - 8 a.m., Monday, June 6, Hall A
- #8047 Health-related quality of life over time in transplant-ineligible patients with newly diagnosed multiple myeloma treated with lenalidomide and dexamethasone until progression - Poster - 8 a.m., Monday, June 6, Hall A

**Pancreatic Cancer:**

- #3020 Phase 2 trial of the indoleamine 2,3-dioxygenase pathway (IDO) inhibitor indoximod plus gemcitabine/nab-paclitaxel for the treatment of metastatic pancreas cancer: Interim analysis - Poster discussion - 4:45 p.m., Sunday,
June 5, Hall B1

- #4104 Final analysis of stage 1 data from a randomized phase II study of PEGPH20 plus nab-Paclitaxel/gemcitabine in stage IV previously untreated pancreatic cancer patients (pts), utilizing Ventana companion diagnostic assay - Poster - 8 a.m., Saturday, June 4, Hall A

- #4113 Optimized economic evaluation for the United States (US) of nab-paclitaxel plus gemcitabine (NAB-P+GEM), FOLFIRINOX (FFX), and gemcitabine (GEM) as first-line treatment for metastatic pancreatic cancer (mPDA) - Poster - 8 a.m., Saturday, June 4, Hall A

- #4114 Evofosfamide combined with gemcitabine/nab-paclitaxel in patients with previously untreated locally advanced or metastatic pancreatic adenocarcinoma (PAC): Results of a phase I trial - Poster - 8 a.m., Saturday, June 4, Hall A

- #4117 Safety, pharmacokinetics, pharmacodynamics, and antitumor activity of necuparanib combined with nab-Paclitaxel and gemcitabine in patients with metastatic pancreatic cancer: Updated phase 1 results - Poster - 8 a.m., Saturday, June 4, Hall A

- #4120 Nab-paclitaxel plus gemcitabine or plus simplified LV5FU2 as first-line therapy in patients with metastatic pancreatic adenocarcinoma: A GERCOR randomized phase II study (AFUGEM) - Poster - 8 a.m., Saturday, June 4, Hall A

- #4124 Impact of second-line treatment (2L T) in advanced pancreatic cancer (APDAC) patients (pts) receiving first line Nab-Paclitaxel (nab-P) + Gemcitabine (G): an Italian multicentre real life experience - Poster - 8 a.m., Saturday, June 4, Hall A

- #6561 Comparative effectiveness of FOLFIRINOX or nab-paclitaxel plus gemcitabine in locally advanced or metastatic pancreatic cancer: A population-based analysis - Poster - 1 p.m., Saturday, June 4, Hall A

Breast Cancer:

- #502 ETNA (Evaluating Treatment with Neoadjuvant Abraxane) randomized phase III study comparing neoadjuvant nab-paclitaxel (nab-P) versus paclitaxel (P) both followed by anthracycline regimens in women with HER2-negative high-risk breast cancer: A MICHELANGELO study - Oral - 1:39 p.m., Monday, June 6, Hall D1

- #1009 Phase Ib trial of atezolizumab in combination with nab-paclitaxel in patients with metastatic triple-negative breast cancer (mTNBC) - Poster discussion - 4:45 p.m., Sunday, June 5, Hall D2

Lymphoma:

- #7538 Feasibility of real-time cell-of-origin subtype identification by gene expression profile in the phase 3 trial of lenalidomide plus R-CHOP vs placebo plus R-CHOP in patients with untreated ABC-type diffuse large B-cell lymphoma (ROBUST) - Poster - 8 a.m., Monday, June 6, Hall A

Myelodysplastic Syndromes:

- #7014 Clinical benefit among lenalidomide (LEN)-treated patients (pts) with RBC transfusion-dependent (RBC-TD) low-/int-1-risk myelodysplastic syndromes (MDS) without del(5q) - Poster discussion - 11:30 a.m., Monday, June 6, E354b

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

For a complete listing of abstracts, visit the ASCO Web site at [http://abstracts.asco.org/](http://abstracts.asco.org/)

*All times Central Daylight Time

**About ABRAXANE®**

ABRAXANE® is indicated for the treatment of breast cancer after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.

ABRAXANE® is indicated for the first-line treatment of locally advanced or metastatic non-small cell lung cancer, in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
ABRAXANE is indicated for the first-line treatment of patients with metastatic adenocarcinoma of the pancreas, in combination with gemcitabine.

Important Safety Information

**WARNING - NEUTROPENIA**

- Do not administer ABRAXANE therapy to patients who have baseline neutrophil counts of less than 1500 cells/mm$^3$. In order to monitor the occurrence of bone marrow suppression, primarily neutropenia, which may be severe and result in infection, it is recommended that frequent peripheral blood cell counts be performed on all patients receiving ABRAXANE.

- Note: An albumin form of paclitaxel may substantially affect a drug’s functional properties relative to those of drug in solution. **DO NOT SUBSTITUTE FOR OR WITH OTHER PACLITAXEL FORMULATIONS**

**CONTRAINDICATIONS**

**Neutrophil Counts**

- ABRAXANE should not be used in patients who have baseline neutrophil counts of < 1500 cells/mm$^3$

**Hypersensitivity**

- Patients who experience a severe hypersensitivity reaction to ABRAXANE should not be rechallenged with the drug.

**WARNINGS AND PRECAUTIONS**

**Hematologic Effects**

- Bone marrow suppression (primarily neutropenia) is dose-dependent and a dose-limiting toxicity of ABRAXANE. In clinical studies, Grade 3-4 neutropenia occurred in 34% of patients with metastatic breast cancer (MBC), 47% of patients with non-small cell lung cancer (NSCLC), and 38% of patients with pancreatic cancer.

- Monitor for myelotoxicity by performing complete blood cell counts frequently, including prior to dosing on Day 1 (for MBC) and Days 1, 8, and 15 (for NSCLC and for pancreatic cancer).

- Do not administer ABRAXANE to patients with baseline absolute neutrophil counts (ANC) of less than 1500 cells/mm$^3$

- In the case of severe neutropenia ( < 500 cells/mm$^3$ for 7 days or more) during a course of ABRAXANE therapy, reduce the dose of ABRAXANE in subsequent courses in patients with either MBC or NSCLC.

- In patients with MBC, resume treatment with every-3-week cycles of ABRAXANE after ANC recovers to a level > 1500 cells/mm$^3$ and platelets recover to a level > 100,000 cells/mm$^3$

- In patients with NSCLC, resume treatment if recommended at permanently reduced doses for both weekly ABRAXANE and every-3-week carboplatin after ANC recovers to at least 1500 cells/mm$^3$ and platelet count of at least 100,000 cells/mm$^3$ on Day 1 or to an ANC of at least 500 cells/mm$^3$ and platelet count of at least 50,000 cells/mm$^3$ on Days 8 or 15 of the cycle.

- In patients with adenocarcinoma of the pancreas, withhold ABRAXANE and gemcitabine if the ANC is less than 500 cells/mm$^3$ or platelets are less than 50,000 cells/mm$^3$ and delay initiation of the next cycle if the ANC is less than 1500 cells/mm$^3$ or platelet count is less than 100,000 cells/mm$^3$ on Day 1 of the cycle. Resume treatment with appropriate dose reduction if recommended.

**Nervous System**

- Sensory neuropathy is dose- and schedule-dependent.

- The occurrence of Grade 1 or 2 sensory neuropathy does not generally require dose modification.

- If ≥ Grade 3 sensory neuropathy develops, withhold ABRAXANE treatment until resolution to Grade 1 or 2 for MBC or until resolution to ≤ Grade 1 for NSCLC and pancreatic cancer followed by a dose reduction for all subsequent courses of ABRAXANE.
Sepsis

- Sepsis occurred in 5% of patients with or without neutropenia who received ABRAXANE in combination with gemcitabine
- Biliary obstruction or presence of biliary stent were risk factors for severe or fatal sepsis
- If a patient becomes febrile (regardless of ANC), initiate treatment with broad-spectrum antibiotics
- For febrile neutropenia, interrupt ABRAXANE and gemcitabine until fever resolves and ANC ≥1500 cells/mm³, then resume treatment at reduced dose levels

Pneumonitis

- Pneumonitis, including some cases that were fatal, occurred in 4% of patients receiving ABRAXANE in combination with gemcitabine
- Monitor patients for signs and symptoms and interrupt ABRAXANE and gemcitabine during evaluation of suspected pneumonitis
- Permanently discontinue treatment with ABRAXANE and gemcitabine upon making a diagnosis of pneumonitis

Hypersensitivity

- Severe and sometimes fatal hypersensitivity reactions, including anaphylactic reactions, have been reported
- Patients who experience a severe hypersensitivity reaction to ABRAXANE should not be rechallenged with this drug

Hepatic Impairment

- Because the exposure and toxicity of paclitaxel can be increased with hepatic impairment, administration of ABRAXANE in patients with hepatic impairment should be performed with caution
- Patients with hepatic impairment may be at an increased risk of toxicity, particularly from myelosuppression, and should be monitored for development of profound myelosuppression
- For MBC and NSCLC, the starting dose should be reduced for patients with moderate or severe hepatic impairment
- For pancreatic adenocarcinoma, ABRAXANE is not recommended for patients with moderate to severe hepatic impairment (total bilirubin > 1.5 x ULN and AST ≤10 x ULN)

Albumin (Human)

- ABRAXANE contains albumin (human), a derivative of human blood

Use in Pregnancy: Pregnancy Category D

- ABRAXANE can cause fetal harm when administered to a pregnant woman
- If this drug is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patient should be apprised of the potential hazard to the fetus
- Women of childbearing potential should be advised to avoid becoming pregnant while receiving ABRAXANE

Use in Men

- Men should be advised not to father a child while receiving ABRAXANE

ADVERSE REACTIONS

Randomized Metastatic Breast Cancer (MBC) Study

- The most common adverse reactions (≥20%) with single-agent use of ABRAXANE vs paclitaxel injection in the MBC study are alopecia (90%, 94%), neutropenia (all cases 80%, 82%; severe 9%, 22%), sensory neuropathy (any
symptoms 71%, 56%; severe 10%, 2%), abnormal ECG (all patients 60%, 52%; patients with normal baseline 35%, 30%), fatigue/asthenia (any 47%, 39%; severe 8%, 3%), myalgia/arthralgia (any 44%, 49%; severe 8%, 4%), AST elevation (any 39%, 32%), alkaline phosphatase elevation (any 36%, 31%), anemia (any 33%, 25%; severe 1%, < 1%), nausea (any 30%, 22%; severe 3%, < 1%), diarrhea (any 27%, 15%; severe < 1%, 1%) and infections (24%, 20%), respectively

- Sensory neuropathy was the cause of ABRAXANE discontinuation in 7/229 (3%) patients
- Other adverse reactions of note with the use of ABRAXANE vs paclitaxel injection included vomiting (any 18%, 10%; severe 4%, 1%), fluid retention (any 10%, 8%; severe 0%, < 1%), mucositis (any 7%, 6%; severe < 1%, 0%), hepatic dysfunction (elevations in bilirubin 7%, 7%), hypersensitivity reactions (any 4%, 12%; severe 0%, 2%), thrombocytopenia (any 2%, 3%; severe < 1%, < 1%), neutropenic sepsis (< 1%, < 1%), and injection site reactions (< 1%, 1%), respectively. Dehydration and pyrexia were also reported
- Renal dysfunction (any 11%, severe 1%) was reported in patients treated with ABRAXANE (n=229)
- In all ABRAXANE-treated patients (n=366), ocular/visual disturbances were reported (any 13%; severe 1%)
- Severe cardiovascular events possibly related to single-agent ABRAXANE occurred in approximately 3% of patients and included cardiac ischemia/infarction, chest pain, cardiac arrest, supraventricular tachycardia, edema, thrombosis, pulmonary thromboembolism, pulmonary emboli, and hypertension
- Cases of cerebrovascular attacks (strokes) and transient ischemic attacks have been reported

Non-Small Cell Lung Cancer (NSCLC) Study

- The most common adverse reactions (≥20%) of ABRAXANE in combination with carboplatin are anemia, neutropenia, thrombocytopenia, alopecia, peripheral neuropathy, nausea, and fatigue
- The most common serious adverse reactions of ABRAXANE in combination with carboplatin for NSCLC are anemia (4%) and pneumonia (3%)
- The most common adverse reactions resulting in permanent discontinuation of ABRAXANE are neutropenia (3%), thrombocytopenia (3%), and peripheral neuropathy (1%)
- The most common adverse reactions resulting in dose reduction of ABRAXANE are neutropenia (24%), thrombocytopenia (13%), and anemia (6%)
- The most common adverse reactions leading to withholding or delay in ABRAXANE dosing are neutropenia (41%), thrombocytopenia (30%), and anemia (16%)
- The following common (≥10% incidence) adverse reactions were observed at a similar incidence in ABRAXANE plus carboplatin-treated and paclitaxel injection plus carboplatin-treated patients: alopecia (56%), nausea (27%), fatigue (25%), decreased appetite (17%), asthenia (16%), constipation (16%), diarrhea (15%), vomiting (12%), dyspnea (12%), and rash (10%); incidence rates are for the ABRAXANE plus carboplatin treatment group
- Adverse reactions with a difference of ≥2%, Grade 3 or higher, with combination use of ABRAXANE and carboplatin vs combination use of paclitaxel injection and carboplatin in NSCLC are anemia (28%, 7%), neutropenia (47%, 58%), thrombocytopenia (18%, 9%), and peripheral neuropathy (3%, 12%), respectively
- Adverse reactions with a difference of ≥5%, Grades 1-4, with combination use of ABRAXANE and carboplatin vs combination use of paclitaxel injection and carboplatin in NSCLC are anemia (98%, 91%), thrombocytopenia (68%, 55%), peripheral neuropathy (48%, 64%), edema peripheral (10%, 4%), epistaxis (7%, 2%), arthralgia (13%, 25%), and myalgia (10%, 19%), respectively
- Neutropenia (all grades) was reported in 85% of patients who received ABRAXANE and carboplatin vs 83% of patients who received paclitaxel injection and carboplatin

Pancreatic Adenocarcinoma Study

- Among the most common (≥20%) adverse reactions in the phase III study, those with a ≥5% higher incidence in the ABRAXANE/gemcitabine group compared with the gemcitabine group are neutropenia (73%, 58%), fatigue (59%, 46%), peripheral neuropathy (54%, 13%), nausea (54%, 48%), alopecia (50%, 5%), peripheral edema (46%, 30%), diarrhea (44%, 24%), pyrexia (41%, 28%), vomiting (36%, 28%), decreased appetite (36%, 26%), rash (30%, 11%), and dehydration (21%, 11%)
- Of these most common adverse reactions, those with a ≥2% higher incidence of Grade 3-4 toxicity in the ABRAXANE/gemcitabine group compared with the gemcitabine group, respectively, are neutropenia (38%, 27%), fatigue (18%, 9%), peripheral neuropathy (17%, 1%), nausea (6%, 3%), diarrhea (6%, 1%), pyrexia (3%, 1%), vomiting (6%, 4%), decreased appetite (5%, 2%), and dehydration (7%, 2%)
Thrombocytopenia (all grades) was reported in 74% of patients in the ABRAXANE/gemcitabine group vs 70% of patients in the gemcitabine group.

The most common serious adverse reactions of ABRAXANE (with a ≥1% higher incidence) are pyrexia (6%), dehydration (5%), pneumonia (4%), and vomiting (4%).

The most common adverse reactions resulting in permanent discontinuation of ABRAXANE were peripheral neuropathy (8%), fatigue (4%), and thrombocytopenia (2%).

The most common adverse reactions resulting in dose reduction of ABRAXANE are neutropenia (10%) and peripheral neuropathy (6%).

The most common adverse reactions leading to withholding or delay in ABRAXANE dosing are neutropenia (16%), thrombocytopenia (12%), fatigue (8%), peripheral neuropathy (15%), anemia (5%), and diarrhea (5%).

Other selected adverse reactions with a ≥5% higher incidence for all-grade toxicity in the ABRAXANE/gemcitabine group compared to the gemcitabine group, respectively, are asthenia (19%, 13%), mucositis (10%, 4%), dysgeusia (16%, 8%), headache (14%, 9%), hypokalemia (12%, 7%), cough (17%, 7%), epistaxis (15%, 3%), urinary tract infection (11%, 5%), pain in extremity (11%, 6%), arthralgia (11%, 3%), myalgia (10%, 4%), and depression (12%, 6%).

Other selected adverse reactions with a ≥2% higher incidence for Grade 3-4 toxicity in the ABRAXANE/gemcitabine group compared to the gemcitabine group are thrombocytopenia (13%, 9%), asthenia (7%, 4%), and hypokalemia (4%, 1%).

Postmarketing Experience With ABRAXANE and Other Paclitaxel Formulations

Severe and sometimes fatal hypersensitivity reactions have been reported with ABRAXANE. The use of ABRAXANE in patients previously exhibiting hypersensitivity to paclitaxel injection or human albumin has not been studied.

There have been reports of congestive heart failure, left ventricular dysfunction, and atrioventricular block with ABRAXANE, primarily among individuals with underlying cardiac history or prior exposure to cardiotoxic drugs.

There have been reports of extravasation of ABRAXANE. Given the possibility of extravasation, it is advisable to monitor closely the ABRAXANE infusion site for possible infiltration during drug administration.

DRUG INTERACTIONS

Caution should be exercised when administering ABRAXANE concomitantly with medicines known to inhibit or induce either CYP2C8 or CYP3A4.

USE IN SPECIFIC POPULATIONS

Nursing Mothers

It is not known whether paclitaxel is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants, a decision should be made to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric

The safety and effectiveness of ABRAXANE in pediatric patients have not been evaluated.

Geriatric

No toxicities occurred notably more frequently among patients ≥65 years of age who received ABRAXANE for MBC.

Myelosuppression, peripheral neuropathy, and arthralgia were more frequent in patients ≥65 years of age treated with ABRAXANE and carboplatin in NSCLC.

Diarrhea, decreased appetite, dehydration, and epistaxis were more frequent in patients 65 years or older compared with patients younger than 65 years old who received ABRAXANE and gemcitabine in adenocarcinoma of the pancreas.

Renal Impairment
There are insufficient data to permit dosage recommendations in patients with severe renal impairment or end stage renal disease (estimated creatinine clearance < 30 mL/min)

**DOSAGE AND ADMINISTRATION**

- Do not administer ABRAXANE to any patient with total bilirubin greater than 5 x ULN or AST greater than 10 x ULN
- For MBC and NSCLC, reduce starting dose in patients with moderate to severe hepatic impairment
- For adenocarcinoma of the pancreas, do not administer ABRAXANE to patients who have moderate to severe hepatic impairment
- Dose reductions or discontinuation may be needed based on severe hematologic, neurologic, cutaneous, or gastrointestinal toxicity
- Monitor patients closely

Please see full Prescribing Information, including Boxed WARNING.

**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](http://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 cardiac failure, occurred more frequently in the REVLIMID treatment arm. REVLIMID is not indicated and not recommended for use in CLL outside of controlled clinical trials.

**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 0.9% respectively

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%), 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 [accompanying or enclosed, etc] full Prescribing Information, including Boxed WARNINGS.

**About POMALYST®**

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

**Important Safety Information**

**WARNING: EMBRYO-FETAL TOXICITY and VENOUS AND ARTERIAL THROMBOEMBOLISM**

**Embryo-Fetal Toxicity**

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

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

**Venous and Arterial Thromboembolism**

- Deep venous thrombosis (DVT), pulmonary embolism (PE), myocardial infarction, and stroke occur in patients with multiple myeloma treated with POMALYST. Prophylactic antithrombotic measures were employed in clinical trials. Thromboprophylaxis is recommended, and the choice of regimen should be based on assessment of the patient's underlying risk factors.

**CONTRAINDICATIONS:** Pregnancy

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

**WARNINGS AND PRECAUTIONS**

**Embryo-Fetal Toxicity**

- Females of Reproductive Potential: Must avoid pregnancy while taking POMALYST and for at least 4 weeks after completing therapy. Must commit either to abstain continuously from heterosexual sexual intercourse or to use 2 methods of reliable birth control, beginning 4 weeks prior to initiating treatment with POMALYST, during therapy, during dose interruptions, and continuing for 4 weeks following discontinuation of POMALYST therapy. Must obtain 2 negative pregnancy tests prior to initiating therapy.
Males: Pomalidomide is present in the semen of patients receiving the drug. Males must always use a latex or synthetic condom during any sexual contact with females of reproductive potential while taking POMALYST and for up to 28 days after discontinuing POMALYST, even if they have undergone a successful vasectomy. Males must not donate sperm.

Blood Donation: Patients must not donate blood during treatment with POMALYST and for 1 month following discontinuation of POMALYST therapy because the blood might be given to a pregnant female patient whose fetus must not be exposed to POMALYST.

POMALYST REMS® Program

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

Venous and Arterial Thromboembolism: Venous thromboembolic events (DVT and PE) and arterial thromboembolic events (ATE) (myocardial infarction and stroke) have been observed in patients treated with POMALYST. In Trial 2, where anticoagulant therapies were mandated, thromboembolic events occurred in 8.0% of patients treated with POMALYST and low-dose-dexamethasone (Low-dose Dex) vs 3.3% treated with high-dose dexamethasone. Venous thromboembolic events (VTE) occurred in 4.7% of patients treated with POMALYST and Low-dose Dex vs 1.3% treated with high-dose dexamethasone. Arterial thromboembolic events include terms for arterial thromboembolic events, ischemic cerebrovascular conditions, and ischemic heart disease. Arterial thromboembolic events occurred in 3.0% of patients treated with POMALYST and Low-dose Dex vs 1.3% treated with high-dose dexamethasone. Patients with known risk factors, including prior thrombosis, may be at greater risk, and actions should be taken to try to minimize all modifiable factors (e.g., hyperlipidemia, hypertension, smoking).

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

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

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

Dizziness and Confusional State: In trials 1 and 2 in patients who received POMALYST + Low-dose Dex, 14% experienced dizziness and 7% a confusional state; 1% of patients experienced Grade 3 or 4 dizziness and 3% experienced a Grade 3 or 4 confusional state. Instruct patients to avoid situations where dizziness or confusional state may be a problem and not to take other medications that may cause dizziness or confusional state without adequate medical advice.

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

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

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

ADVERSE REACTIONS

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

**DRUG INTERACTIONS**

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

**USE IN SPECIFIC POPULATIONS**

**Pregnancy:** If pregnancy does occur during treatment, immediately discontinue the drug and refer patient to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling. Report any suspected fetal exposure to POMALYST to the FDA via the MedWatch program at 1-800-332-1088 and also to Celgene Corporation at 1-888-423-5436.

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

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

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

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

Please see full [Prescribing Information](#), including Boxed WARNINGS.

**About Celgene**

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases through next-generation solutions in protein homeostasis, immuno-oncology, epigenetics, immunology and neuro-inflammation. For more information, please visit [www.celgene.com](http://www.celgene.com). Follow Celgene on Social Media: [@Celgene](https://twitter.com/Celgene), [Pinterest](https://www.pinterest.com/Celgene/), [LinkedIn](https://www.linkedin.com/company/celgene-corporation), [Facebook](https://www.facebook.com/Celgene) and [YouTube](https://www.youtube.com/Celgene).

**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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