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**REVLIMID<sup>®</sup> IN COMBINATION WITH DEXAMETHASONE sNDA  
GRANTED APPROVAL BY FDA FOR TREATMENT OF MULTIPLE  
MYELOMA**

*Third FDA Approval For Celgene Corporation in Six Months*

**SUMMIT, NJ – (June 29, 2006)** – Celgene Corporation (NASDAQ: CELG) announced that the U.S. Food and Drug Administration (FDA) has granted approval for its Supplemental New Drug Application (sNDA) for an additional indication for REVLIMID (lenalidomide), for use in combination with dexamethasone as a treatment for patients with multiple myeloma who have received at least one prior therapy. REVLIMID is also approved for use in the treatment of patients with transfusion-dependent anemia due to Low-or-Intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Multiple myeloma is the second most common blood cancer in the United States, affecting approximately 50,000 people. About 14,600 new cases of multiple myeloma are diagnosed each year and about 12,000 Americans are expected to die of multiple myeloma in 2006.

In the REVLIMID (lenalidomide)/dexamethasone treatment group, 151 patients (45%) underwent at least one dose interruption with or without a dose reduction of REVLIMID (lenalidomide) compared to 21% in the placebo/dexamethasone treatment group. Most adverse events and Grade 3 or 4 adverse events were more frequent in patients who received the combination of REVLIMID (lenalidomide)/dexamethasone compared to placebo/dexamethasone.

“The FDA approval of REVLIMID offers a new oral therapeutic option to this particular group of patients with multiple myeloma,” said Graham Burton, M.D., SVP, Regulatory Affairs and Pharmacovigilance for Celgene.

REVLIMID will be available in the following strengths: 5 mg, 10 mg, 15 mg, and 25 mg capsules.

**SAFETY NOTICE:**

**WARNINGS:**

**1. POTENTIAL FOR HUMAN BIRTH DEFECTS.**

LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. FEMALES SHOULD BE ADVISED TO AVOID PREGNANCY WHILE TAKING REVLIMID® (lenalidomide).

**Special Prescribing Requirements**

BECAUSE OF THIS POTENTIAL TOXICITY AND TO AVOID FETAL EXPOSURE TO REVLIMID (lenalidomide), REVLIMID (lenalidomide) IS ONLY AVAILABLE UNDER A SPECIAL RESTRICTED DISTRIBUTION PROGRAM. THIS PROGRAM IS CALLED “RevAssist<sup>SM</sup>”. UNDER THIS PROGRAM, ONLY PRESCRIBERS AND PHARMACISTS REGISTERED WITH THE PROGRAM CAN PRESCRIBE AND DISPENSE THE PRODUCT. IN ADDITION, REVLIMID (lenalidomide) MUST ONLY BE DISPENSED TO PATIENTS WHO ARE REGISTERED AND MEET ALL THE CONDITIONS OF THE RevAssist<sup>SM</sup> PROGRAM.

**2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).**

THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA. EIGHTY PERCENT OF PATIENTS WITH DELETION 5Q MYELODYSPLASTIC SYNDROMES 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 DELETION 5Q MYELODYSPLASTIC SYNDROMES 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. (SEE DOSAGE AND ADMINISTRATION)

**3. DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM.**

THIS DRUG HAS DEMONSTRATED A SIGNIFICANTLY INCREASED RISK OF DEEP VENOUS THROMBOSIS (DVT) AND PULMONARY EMBOLISM (PE) IN PATIENTS WITH MULTIPLE MYELOMA WHO WERE TREATED WITH REVLIMID (lenalidomide) COMBINATION THERAPY. PATIENTS AND PHYSICIANS ARE ADVISED TO BE OBSERVANT FOR THE SIGNS AND SYMPTOMS OF THROMBOEMBOLISM. PATIENTS SHOULD BE INSTRUCTED TO SEEK MEDICAL CARE IF THEY DEVELOP SYMPTOMS SUCH AS SHORTNESS OF BREATH, CHEST PAIN, OR ARM OR LEG SWELLING. IT IS NOT KNOWN WHETHER PROPHYLACTIC ANTICOAGULATION OR ANTIPLATELET THERAPY PRESCRIBED IN CONJUNCTION WITH REVLIMID (lenalidomide) MAY LESSEN THE POTENTIAL FOR VENOUS THROMBOEMBOLIC EVENTS. THE DECISION TO TAKE PROPHYLACTIC MEASURES SHOULD BE DONE CAREFULLY AFTER AN ASSESSMENT OF AN INDIVIDUAL PATIENT’S UNDERLYING RISK FACTORS.

You can get information about REVLIMID (lenalidomide) and the RevAssist<sup>SM</sup> program on the Internet at [www.REVLIMID.com](http://www.REVLIMID.com) or by calling the manufacturer’s toll-free number at 1-888-423-5436.

## **IMPORTANT SAFETY INFORMATION**

**Hypersensitivity:** REVLIMID<sup>®</sup> (lenalidomide) is contraindicated in any patients who have demonstrated hypersensitivity to the drug or its components.

**Renal impairment:** REVLIMID (lenalidomide) is substantially excreted by the kidney, so the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it would be prudent to monitor renal function.

**Nursing mothers:** It is not known whether REVLIMID (lenalidomide) is excreted in human milk. 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.

**Other adverse events:** Multiple Myeloma (REVLIMID/dexamethasone) constipation (39%), fatigue (38%), insomnia (32%), muscle cramp (30%), diarrhea (29%), neutropenia (28%), anemia (24%), asthenia (23%), pyrexia (23%), nausea (22%), headache ((21%), peripheal edema (21%), dizziness (21%), dyspnea (20%), tremor (20%), decreased weight (18%), thrombocytopenia (17%), rash (16%), back pain (15%), hyperglycemia (15%), and muscle weakness (15%).

**Deletion 5q MDS (REVLIMID):** 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%), and pharyngitis (16%).

### **About REVLIMID<sup>®</sup>**

REVLIMID is a member of a proprietary group of novel immunomodulatory agents. Celgene continues to evaluate REVLIMID in a broad range of hematological and oncological conditions. The IMiDs<sup>®</sup> pipeline, including REVLIMID, is covered by a comprehensive intellectual property estate of U.S. and foreign issued and pending patent applications including composition-of-matter and use patents.

REVLIMID is indicated for use as a treatment in combination with dexamethasone for previously treated multiple myeloma. REVLIMID is also indicated for 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.

### **About RevAssist<sup>SM</sup>**

FOR FURTHER INFORMATION ABOUT REVLIMID AND THE RevAssist PROGRAM, YOU MAY GO TO THE INTERNET AT [www.REVLIMID.com](http://www.REVLIMID.com) OR BY CALLING THE MANUFACTURER'S TOLL FREE NUMBER 1-888-4CELGENE. RevAssist<sup>SM</sup> is a proprietary risk-management restrictive distribution program, tailored specifically for REVLIMID patients, to prevent the potential for human birth defects and ensure prompt and convenient access to REVLIMID.

### **About Multiple Myeloma**

Multiple myeloma (also known as myeloma or plasma cell myeloma) is a cancer of the blood in which malignant plasma cells are overproduced in the bone marrow. Plasma cells are white blood cells that help produce antibodies called immunoglobulins that fight infection and disease.

However, most patients with multiple myeloma have cells that produce a form of immunoglobulin called paraprotein (or M protein) that does not benefit the body. In addition, the malignant plasma cells replace normal plasma cells and other white blood cells important to the immune system. Multiple myeloma cells can also attach to other tissues of the body, such as bone, and produce tumors. The cause of the disease remains unknown.

In the year 2005, there were approximately 200,000 people worldwide suffering from multiple myeloma. An estimated 74,000 new cases of multiple myeloma are expected in 2006. The estimated number of deaths from multiple myeloma expected in 2006 is approximately 60,000 worldwide. Average survival time for a patient diagnosed with multiple myeloma is about three to four years.

### **About Myelodysplastic Syndromes**

Myelodysplastic syndromes (MDS) are a group of hematologic malignancies that affect approximately 300,000 people worldwide. Myelodysplastic syndromes occur when blood cells remain in an immature or "blast" stage within the bone marrow and never develop into mature cells capable of performing their necessary functions. Eventually, the bone marrow may be filled with blast cells suppressing normal cell development. According to the American Cancer Society, 10,000 to 20,000 new cases of MDS are diagnosed each year in the United States, with mean survival rates ranging from approximately six months to six years for the different classifications of MDS. MDS patients must often rely on blood transfusions to manage symptoms of anemia and fatigue and may develop life-threatening iron overload and/or toxicity from frequent transfusions, thus underscoring the critical need for new therapies targeting the cause of the condition rather than simply managing its symptoms.

### **About Deletion 5q Chromosomal Abnormality**

Chromosomal (cytogenetic) abnormalities are detected in more than half of patients with myelodysplastic syndrome (MDS), and involve a deletion in all or part of one or more specific chromosomes. The most common cytogenetic abnormalities in MDS are deletions in the long arm of chromosomes 5, 7, and 20. Another common abnormality is an extra copy of chromosome 8. A deletion involving the 5q chromosome may be involved in 20 to 30 percent of all MDS patients. The World Health Organization has also recently identified a unique subset of MDS patients with a "5q- Syndrome" where the only chromosomal abnormality is a specific portion of the 5q chromosome.

### **Webcast**

Celgene will host a conference call on June 30, 2006 at 8:30 a.m. EDT to discuss the FDA approval of REVLIMID<sup>®</sup>. The conference call will be available by webcast at [www.celgene.com](http://www.celgene.com). An audio replay of the call will be available from noon EDT June 30, 2006 until midnight EDT July 10, 2006. To access the replay, dial 1-800-642-1687 and enter Reservation Number 2521167.

### **About Celgene**

Celgene Corporation, headquartered in Summit, New Jersey, is an integrated global pharmaceutical company engaged primarily in the discovery, development and commercialization of innovative therapies for the treatment of cancer and inflammatory diseases

through gene and protein regulation. For more information, please visit the Company's website at [www.celgene.com](http://www.celgene.com).

REVLIMID® is a registered trademark of Celgene Corporation.

RevAssist<sup>SM</sup> is a service mark of Celgene Corporation.

*This release contains forward-looking statements which are subject to known and unknown risks, delays, uncertainties and other factors not under the Company's control, which may cause actual results, performance or achievements of the Company to be materially different from the results, performance or other expectations expressed or implied by these forward-looking statements. These factors include results of current or pending research and development activities, actions by the FDA and other regulatory authorities, and other factors described in the Company's filings with the Securities and Exchange Commission such as our 10K, 10Q and 8K reports.*

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