

## **Presseerklärung der Celgene Corp.**

### **Thalomid® sNDA Granted FDA Approval For Treatment of Newly Diagnosed Multiple Myeloma**

Summit, NJ (May 25, 2006) - Celgene Corporation (Nasdaq: CELG) announced that the U.S. Food and Drug Administration (FDA) has granted accelerated approval to its Supplemental New Drug Application (sNDA) for THALOMID (thalidomide) in combination with dexamethasone for the treatment of newly diagnosed multiple myeloma. The effectiveness of THALOMID is based upon response rates. There are no controlled trials demonstrating a clinical benefit, such as an improvement in survival. 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.

THALOMID is available through a THALOMID Education and Prescribing Safety System, called S.T.E.P.S.(R). Through the use of our S.T.E.P.S. program, more than 130,000 U.S. patients have had safe access to THALOMID since its market introduction in July 1998. This FDA approval for the indication of THALOMID in the treatment of newly diagnosed multiple myeloma allows physicians and their patients to be treated with another therapy option for this incurable blood cancer.

The safety profile for THALOMID in multiple myeloma has shown an increase in side effects with THALOMID and dexamethasone as compared to dexamethasone alone. The most common adverse events were constipation, sensory neuropathy, confusion, hypocalcemia, edema, dyspnea, thrombosis/embolism, and rash/desquamation, occurring in 20% of patients with a frequency less than or equal to 10% in patients treated with THALOMID/dexamethasone compared with dexamethasone alone.

"The approval of our sNDA represents a significant milestone for Celgene and an important step toward fulfilling our mission of making innovative treatment options available to patients with significant unmet medical needs," said Sol Barer, Ph.D., Chief Executive Officer at Celgene. "We are committed to the ongoing clinical development of our investigational therapies being studied in blood and solid tumor cancers, and we are proud that our efforts have resulted in this approval of THALOMID for use in combination with dexamethasone in newly diagnosed multiple myeloma patients."

#### **Safety Notice**

THALOMID(R) (thalidomide) Capsules 50 mg, 100 mg, & 200 mg

**WARNING:** If thalidomide is taken during pregnancy, it can cause severe birth defects or death to an unborn baby. Thalidomide should never be used by women who are pregnant or who could become pregnant while taking the drug. Even a single dose, one capsule (50 mg, 100 mg and 200 mg), taken by a pregnant woman can cause severe

birth defects. Because thalidomide is present in the semen of male patients, males receiving thalidomide must always use a latex condom during sexual contact with women of childbearing potential even if he has undergone a successful vasectomy. Thalidomide can only be marketed under a special restricted distribution program. This program is called the "System for Thalidomide Education and Prescribing Safety (S.T.E.P.S.®)". Under this program, only registered prescribers and pharmacists may dispense the drug. In addition, patients must be advised of, agree to and comply with the requirements of S.T.E.P.S.

The use of Thalomid® (thalidomide) in multiple myeloma results in an increased risk of venous thromboembolic events, such as deep venous thrombosis and pulmonary embolus. This risk increases significantly when thalidomide is used in combination with standard chemotherapeutic agents including dexamethasone. In one controlled trial, the rate of venous thromboembolic events was 22.5% in patients receiving thalidomide in combination with dexamethasone compared to 4.9% in patients receiving dexamethasone alone ( $p = 0.002$ ). 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. Preliminary data suggests that patients who are appropriate candidates may benefit from concurrent prophylactic anticoagulation or aspirin treatment.

Thalidomide is contraindicated in patients who have demonstrated hypersensitivity to the drug and its components. It is not known whether THALOMID 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. Thalidomide is known to cause nerve damage that may be permanent. Peripheral neuropathy is a common, potentially severe, side effect of treatment with thalidomide that may be irreversible. Decreased white blood cell counts, including neutropenia, have been reported in the clinical use of thalidomide. In placebo controlled clinical trials of HIV-seropositive patient populations, there have been reports of increased plasma HIV RNA levels associated with thalidomide therapy. The most frequently reported adverse events were constipation (55%), sensory neuropathy (54%), confusion (28%), hypocalcemia (72%), edema (57%), dyspnea (42%), thrombosis/embolism (23%), and rash/desquamation (30%) (occurring in >20% of patients and with a frequency >10% in patients treated with THALOMID/dexamethasone compared with dexamethasone alone). Patients should be advised about these associated adverse events and routinely monitored by a physician during treatment with thalidomide. Patients should be instructed to not extensively handle or open thalidomide capsules and to maintain storage of capsules in blister packs until ingestion.

### **About THALOMID®**

THALOMID (thalidomide), manufactured by Celgene Corporation, received U.S. Food and Drug Administration (FDA) clearance on July 16, 1998 for the acute treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL) and as maintenance therapy for prevention and suppression of the cutaneous

manifestations of ENL recurrence. Thalidomide is not indicated as monotherapy for ENL treatment in the presence of moderate to severe neuritis. Thalidomide is indicated for use as a treatment in combination with dexamethasone for newly diagnosed multiple myeloma.

### **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.

### **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).

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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