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# REVLIMID® NEW DRUG APPLICATION SUBMITTED TO FDA FOR REVIEW

 Clinical Data From Phase II Trial (MDS-003) in Patients with Myelodysplastic Syndromes with 5q Deletion Chromosomal Abnormality Submitted

**SUMMIT, NJ** – (**April 8, 2005**) –Celgene Corporation (NASDAQ: CELG) announced that it has completed the rolling submission of its New Drug Application (NDA) for REVLIMID (lenalidomide), an investigational drug, to the Division of Oncology Drug Products at the U.S. Food and Drug Administration (FDA) for review. The Company's NDA is seeking approval to market REVLIMID as a treatment for transfusion-dependent patients with myelodysplastic syndromes (MDS) with a 5q deletion chromosomal abnormality.

MDS is a malignant disorder of blood cell production that affects approximately 300,000 people worldwide. The most common clinical manifestation associated with MDS is refractory anemia, and the multiple complications that stem from frequent blood transfusions. Celgene's lead IMiD® (Immunomodulatory drug), REVLIMID has received both orphan drug status and fast track designation from the U.S. Food and Drug Administration (FDA) and orphan drug status from the European Agency for the Evaluation of Medicinal Products for the treatment of MDS.

"Celgene appreciates and acknowledges the efforts of all those who made this filing possible, including: the more than 400 patients who participated in these MDS studies, and the international community of clinical investigators who have helped us get to this stage in the regulatory process." said Jerome B. Zeldis, M.D., Ph.D., Chief Medical Officer and VP, Medical Affairs of Celgene Corporation.

# **About REVLIMID®**

REVLIMID is a member of a new class of novel immunomodulatory drugs, or IMiDs<sup>®</sup>. Celgene is evaluating treatments with REVLIMID for a broad range of hematology and oncology conditions, including; multiple myeloma, the malignant blood cell disorders known as myelodysplastic syndromes (MDS) as well as solid tumor cancers. REVLIMID affects multiple intracellular biological pathways. The IMiD 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<sup>®</sup> (lenalidomide) is not approved by the FDA or any other regulatory agencies as a treatment in any indication and is currently being evaluated in clinical trials for efficacy and safety for future regulatory applications.

### **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 until they develop life-threatening iron overload and/or toxicity, thus underscoring the critical need for new therapies targeting the cause of the condition rather than simply managing its symptoms.

# **About 5q Deletion 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% 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.

#### **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.

This release contains certain forward-looking statements which involve 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 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 those factors detailed in the Company's filings with the Securities and Exchange Commission such as 10K, 10Q and 8K reports.