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## **REVLIMID<sup>®</sup> Pivotal Phase III Multiple Myeloma Trials Both Exceed Pre-Specified Interim Efficacy Endpoint**

- **Independent Data Monitoring Committee review determines that both Phase III Special Protocol Assessment pivotal trials overwhelmingly exceeded the pre-established efficacy stopping rule of  $p < 0.0015$  for the primary endpoint, time to disease progression**
- **Celgene will unblind the studies and allow all patients in these studies access to REVLIMID**
- **Discussions with FDA and international agencies are ongoing**
- **Plans being formulated to create expanded access programs for patients with previously treated myeloma**

**SUMMIT, NJ – (March 7, 2005) – Celgene Corporation (NASDAQ: CELG)** announced that external Independent Data Monitoring Committee analyses of both Phase III Special Protocol Assessment (SPA) multiple myeloma trials exceeded the pre-specified  $p < 0.0015$  value for stopping the trials. The IDMC found a statistically significant improvement in time to disease progression - the primary endpoint of these Phase III trials - in patients receiving REVLIMID plus dexamethasone compared to patients receiving dexamethasone alone. Celgene has initiated discussions with the FDA and international regulatory authorities regarding the submission of this data for potential approval. Treatment assignments for patients currently on the trials will be unblinded and those currently not on REVLIMID will have the opportunity to add REVLIMID to their dexamethasone regimen.

Based on these highly significant results, Celgene is planning REVLIMID expanded access programs for patients in the US and in Europe who have previously treated multiple myeloma.

"Following preliminary analysis we plan to use this data as the basis of a regulatory submission to the FDA and EMEA for REVLIMID in previously treated multiple myeloma patients." said Jerome B. Zeldis, M.D., Ph.D., Chief Medical Officer and VP, Medical Affairs of Celgene Corporation.

The REVLIMID Phase III trials included patients with relapsed or refractory multiple myeloma. Patients were randomized to receive REVLIMID plus dexamethasone or dexamethasone alone. The trials enrolled 705 patients and are being conducted in 97 sites internationally. The trial design included a primary endpoint of time to disease progression calculated as the time from randomization to the first documentation of progressive disease based on Bladé myeloma response criteria.

In addition to the initial positive efficacy profile, the preliminary safety profile was favorable. All data are being analyzed further for the regulatory submissions.

### **About REVLIMID®**

REVLIMID is a member of a new class of novel immunomodulatory drugs, or IMiDs®. 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 patents and pending patent applications including composition-of-matter and use patents.

REVLIMID (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 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.

Multiple myeloma is the second most common cancer of the blood, representing approximately one percent of all cancers and two percent of all cancer deaths with a worldwide prevalence of approximately 200,000 cases. In the year 2004, there were an estimated 74,000 new cases of multiple myeloma worldwide. The estimated number of deaths from multiple myeloma in 2005 was about 60,000 worldwide.

### **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 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.*

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