Positive Interim Results Presented at the VIIIth International Myeloma Workshop on Celgene Corporation's Lead IMiD(TM) (REVIMID(TM))

Lead Investigators from Dana-Farber Cancer Institute and the Arkansas Cancer

Research Center Reported on REVIMID's Activity and Safety Profile

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BANFF, Alberta, May 8 /PRNewswire/ -- Celgene Corporation (Nasdaq: CELG) today announced that investigators from the Arkansas Cancer Research Center and Dana-Farber Cancer Institute presented preliminary results on REVIMID(TM), Celgene's lead Immunomodulatory Drug (IMiD(TM)) for the treatment of multiple myeloma. Bart Barlogie, M.D., Ph.D., Director of the Arkansas Cancer Research Center and Kenneth C. Anderson, M.D. and Paul G. Richardson, M.D. of Dana-Farber Cancer Institute and Harvard Medical School presented interim data at the VIIIth International Myeloma Workshop on Phase I/II trials studying REVIMID's potential safety and efficacy in multiple myeloma patients. More than sixty percent of these late stage patients who had progressive disease were responding or had their disease stabilized on the REVIMID therapy. Those patients who experienced improvement continued to improve as therapy progressed. The investigators also reported that no dose limiting toxicities were observed and as a result, a maximum tolerated dose has not yet been determined. Ongoing studies will observe the tolerability and therapeutic activity of escalating doses of REVIMID.

"These encouraging results are the first major step in the validation of our IMiD class of drugs and reflect the exciting potential of this novel compound," said Sol J. Barer, Ph.D., President and Chief Operating Officer of Celgene Corporation. "We will now significantly accelerate our clinical and regulatory programs in multiple myeloma and other oncology indications."

IMiDs are novel, small-molecule, orally available analogs of thalidomide that are designed to be more potent and potentially have a better safety profile than the parent compound. Celgene's IMiDs have significantly greater immunological activity in in vitro studies. IMiDs were reported in the November 1, 2000 issue of BLOOD to enhance T-cell proliferation and interleukin (IL)-2 production. In the same report, IMiDs were also shown to be potent inhibitors of inflammatory cytokines that include TNF-alpha and IL-1beta while stimulating the anti-inflammatory cytokine IL-10. IMiDs, including Celgene's current lead clinical candidate REVIMID, are covered by issued and pending patents in the U.S. and internationally.

Dr. Bart Barlogie reported on the treatment of twelve refractory multiple myeloma patients in a four week, open-label safety trial. The study included eleven patients who have completed four weeks of REVIMID monotherapy treatment and one patient who had completed two weeks of therapy. Four patient cohorts, of three patients each, received a daily dose of 5 mg, 10 mg, 25 mg, and 50 mg of REVIMID, respectively. Patients were evaluated by reductions in levels of paraproteins, which are validated clinical markers associated with corresponding reduction in bone marrow plasmacystosis, recovery from anemia/thrombocytopenia and uninvolved immunoglobulins.

To date, in all four dosing levels, patients tolerated the treatment well with no grade four toxicities observed. Adverse effects noted were mild to moderate rash not necessitating dose modification and reductions in the granulocyte count. Neither sedation nor constipation, common side effects of thalidomide treatment, were observed. No peripheral neuropathy developed during therapy and those who had peripheral neuropathy at study entry did not have this symptom exacerbated during the course of the trial.

Improved response was seen with higher dosages of REVIMID. During the first four weeks of therapy, four patients had a greater than 25 percent reduction of paraprotein levels including one patient experiencing a 75 percent reduction in paraprotein levels. All three patients at the highest dose level (50 mg/day) were responding. Three patients had progressive disease

thalidomide-resistant or had poor cytogenetics," said Dr. Barlogie. "Because this drug is so well tolerated, we plan to use higher levels to define the maximum tolerated dose."

Results of the open-label safety trial conducted at Dana-Farber Cancer Institute were also presented by Dr. Kenneth C. Anderson and Dr. Paul G. Richardson. The study included patients with rapidly advancing refractory multiple myeloma, nine of whom had failed thalidomide and multiple other therapies and ten of whom had prior bone marrow transplants. Side effects in this study were consistent with those reported in the University of Arkansas study, which included rash and a decrease in white blood cell count. No sedation, constipation or exacerbation of peripheral neuropathy were observed. Treatment with REVIMID up to 25 mg per day was well tolerated, with seven of eleven evaluable patients demonstrating a response to the drug. Four patients had progressive disease. Of those who were responding to the drug, one patient experienced a greater than 50 percent reduction in paraprotein levels and five patients had between a 25 and 50 percent reduction in paraprotein levels.

"These data lay a promising foundation for what may be a whole new approach to the treatment of multiple myeloma, with possible substantial improvements in outcomes and patient quality of life," said Dr. Anderson. "We anticipate a highly productive clinical trial program with REVIMID for multiple myeloma."

About Multiple Myeloma

There are approximately 40,000 people in the United States living with multiple myeloma and 14,400 new cases of multiple myeloma are diagnosed each year in the United States, making it the second most common blood cancer. Incurable with conventional chemotherapy, multiple myeloma is a malignant cancer of the plasma cells, which are a type of white blood cells, found in many tissues of the body, but mainly in the bone marrow. As the cancer grows it destroys normal bone tissue, causing pain and crowding out normal blood cell production. There are nearly 11,200 deaths expected during 2001, according to the Multiple Myeloma Research Foundation.

In addition to studies presented the VIIIth International Myeloma Workshop, Celgene is currently conducting Phase I/II studies of REVIMID in the United Kingdom in solid tumors, including malignant melanoma and pancreatic cancer. A congestive heart failure trial with REVIMID will commence this quarter in the United States.

Celgene Corporation will host its first annual Analyst and Investor Day on June 7, 2001 in New York City where the progress of the IMiDs and the entire Celgene product pipeline will be more fully discussed. An invitation to this event can be requested by visiting Celgene's website at http://www.celgene.com.

Celgene Corporation, headquartered in Warren, New Jersey, is an independent biopharmaceutical company engaged in the discovery, development and commercialization of small molecule drugs for cancer and immunological diseases.

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