Celgene Corporation Receives Orphan Drug Designation for Revimid(TM) For Multiple Myeloma

PR Newswire

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Body

Celgene Corporation (Nasdaq: CELG) announced today that REVIMID(TM), the Company's lead IMiD(TM) (Immunomodulatory Drug), has been granted orphan drug designation by the U.S. Food and Drug Administration (FDA) for multiple myeloma. Orphan drug status entitles Celgene to seven years of market exclusivity in multiple myeloma for REVIMID following FDA approval.

The IMiDs are novel, small molecule, orally available analogs of thalidomide that are designed to be more potent and have demonstrated a better safety profile in clinical trials than the parent compound. Celgene's IMiDs have significantly greater immunological activity than thalidomide in in vitro studies. Data published in The Journal of Immunology demonstrated that IMiDs potently inhibit the inflammatory cytokines TNF-alpha and interleukin (IL)-1 beta while stimulating the anti-inflammatory cytokine IL-10. IMiDs were also reported in Blood to enhance T-cell proliferation and IL-2 production. REVIMID and the IMiD pipeline are 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.

REVIMID is being evaluated as a multiple myeloma therapy in two Phase I/II clinical trials at the Arkansas Cancer Research Center and the Dana-Farber Cancer Institute. In May, at the International Myeloma Workshop, Bart Barlogie, M.D., Ph.D. from the Arkansas Cancer Research Center and Ken Anderson, M.D. from the Dana-Farber Cancer Institute presented interim data from both trials. They reported that 60 percent of the late-stage multiple myeloma patients who had progressive disease were responding or had their disease stabilized on REVIMID therapy.
Importantly, patients who experienced improvement continued to improve as therapy progressed. The investigators also reported that neither sedation nor constipation, common side effects of thalidomide treatment, was observed. Adverse effects noted were mild to moderate rash and reductions in white blood cell counts. Drs. Barlogie and Anderson are expected to present current interim data from the trials in December at the annual meeting of the American Society of Hematology.

REVIMID also completed the initial phase of a clinical trial in metastatic melanoma, and based on the results, the trial is being expanded to an additional 60 patients who will be treated at greater than 100 mg/day. Further studies are planned for REVIMID in anti-inflammatory diseases, in addition to a recently initiated congestive heart failure trial.

About Multiple Myeloma

There are approximately 40,000 people in the United States living with multiple myeloma. It is the second most common blood cancer, with 14,000 new cases of multiple myeloma diagnosed each year in the United States. Incurable with conventional chemotherapy, multiple myeloma is a malignant cancer of the plasma cell, which is a type of white blood cell, found in many tissues of the body, but mainly in the bone marrow. As the cancer grows it

deaths expected during 2001, according to the Multiple Myeloma Research Foundation and the American Cancer Society.

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

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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