



Contact: Robert J. Hugin
Senior VP and CFO
Celgene Corporation
(908) 673-9102

Brian P. Gill
Director PR/IR
Celgene Corporation
(908) 673-9530

FDA ONCOLOGIC DRUGS ADVISORY COMMITTEE RECOMMENDS REVLIMID[®] FOR FULL APPROVAL

*By a 10-5 vote, ODAC Recommends REVLIMID As Oral Targeted Therapy For
Low To Intermediate-1-Risk MDS Patients With Deletion
5q Chromosomal Abnormality*

- FDA PDUFA date October 7, 2005 -

WASHINGTON (September 14, 2005) – Celgene Corporation (NASDAQ: CELG) announced that the Oncologic Drugs Advisory Committee (ODAC) of the U.S. Food and Drug Administration (FDA) recommended full approval of REVLIMID (lenalidomide) for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. The committee based its recommendation on clinical data from an open label Phase II trial, evaluating REVLIMID in the largest trial with MDS patients with deletion 5q chromosomal abnormality to date. The data showed that:

- Approximately two-thirds of patients achieved resolution of chronic refractory anemia resulting in transfusion independence
- Response was associated with meaningful cytogenetic and bone marrow remission
- Responder median hemoglobin increased more than 5.0 grams per deciliter
- After median follow-up of 58 weeks, the median duration of transfusion-independence response had not yet been reached
- The dosing in the study was based on tolerability and additional studies are planned to refine dosing
- The major side effects were cytopenias leading to dose reductions

“We are excited about ODAC’s positive recommendation for approval of this NDA. REVLIMID will offer the opportunity to improve the lives of deletion 5q MDS patients with limited therapeutic options beyond blood transfusions,” said John W. Jackson, Chairman and Chief Executive Officer, Celgene Corporation.

About REVLIMID[®]

REVLIMID is a member of a new class of novel IMiDs[®], immunomodulatory drugs. Celgene continues to evaluate 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), chronic lymphocytic leukemia 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.

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 ODAC

ODAC evaluated the REVLIMID NDA for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Both Celgene and the FDA presented the results of the open label Phase II (MDS-003) trial data.

These questions were voted upon by the committee:

Question #1: Randomized controlled trials allowed for direct comparisons of treatment effects and safety between treatment arms. A single arm study has been submitted using an 8-week run-in period to serve as a baseline for each patient's transfusion requirements. A comparison is subsequently made to a follow-up 8-week period on Revlimid to compare transfusion requirements. Does this study design allow adequate characterization of Revlimid's treatment effect in the population described in the proposed indication? Vote 11 Yes - 4 No

Question #2: In this single arm trial, 80% of patients enrolled in MDS-003 has dose reductions and/or delays and 80% of patients experienced either grade 3 or 4 adverse events. Data do not exist on the efficacy and safety of lower Revlimid doses. Approval of a drug is contingent upon being able to write adequate product labeling, requiring a recommended dose and

characterization of a safety profile. Do the data provided in this single-arm trial provide a basis for a recommendation dose and adequate description of a safety profile? Vote 2 Yes –13 No

Question #3: Please characterize the magnitude of the benefit and risk of REVLIMID[®] in the indication being sought. After this characterization, does this risk/benefit analysis warrant approval? Vote 10 Yes -5 No

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 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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