

REVLIMID (R) (Lenalidomide) Survival Data Evaluated in Previously Treated Multiple Myeloma

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- Clinical Data Evaluating Lenalidomide in Multiple Myeloma Reported at 11th Congress of European Hematology Association Meeting

Celgene International Sarl, a wholly owned subsidiary of Celgene Corporation, announced clinical data from two multi-centered, randomized, double-blind, placebo-controlled Phase III pivotal studies evaluating lenalidomide plus dexamethasone in previously treated patients with multiple myeloma were presented at the 11th Congress of the European Hematology Association (EHA) in Amsterdam, Netherlands on Saturday, June 17, 2006.

The updated clinical data from the pivotal International Phase III trial (MM-010) reported overall survival ($p=0.03$) in addition to median time to disease progression ($p<0.0001$). As of June 2006, median overall survival in the International trial in patients treated with lenalidomide plus dexamethasone has not been reached as compared to 20.6 months with dexamethasone plus placebo. The clinical data from the pivotal North American Phase III trial (MM-009) reported overall survival ($p=0.0001$) in addition to median time to disease progression ($p<0.0001$).

The data were presented at an oral session by Meletios Dimopoulos, M.D., Professor of Therapeutics at The University of Athens School of Medicine, Greece. Dr. Dimopoulos also presented updated results from the International Phase III special protocol assessment trial (MM-010). Data from the International study reported that:

- The median overall survival (OS) in patients treated with lenalidomide plus dexamethasone has not been reached compared with 20.6 months for dexamethasone plus placebo ($p=0.03$)
- The median time-to-disease progression (TTP) with lenalidomide plus dexamethasone was 11 months, compared with 5 months for dexamethasone plus placebo ($p<0.001$)
- Overall response rate with lenalidomide plus dexamethasone was 59 percent compared with 24 percent for dexamethasone plus placebo ($p<0.001$)
- Complete response (CR) rate (based on EBMT criteria) with lenalidomide plus dexamethasone was 15 percent, compared with 3.4 percent for dexamethasone plus placebo ($p<0.001$)
- The most common side effects observed in this trial with the combination of lenalidomide and dexamethasone were constipation, diarrhea and neutropenia

Among the 63 second-line multiple myeloma patients (those who had only one prior therapy), Revlimid plus dexamethasone was superior based on time to progression ($p=0.003$) and response rate ($p=0.008$). Additional findings include the following:

- The median TTP has not been reached for patients who have received lenalidomide plus dexamethasone as compared to 5 months for patients who received dexamethasone plus placebo
- Overall response rate with lenalidomide plus dexamethasone was 67 percent compared with 33 percent for dexamethasone; and

-- Complete response with lenalidomide plus dexamethasone was 27 percent compared with 3 percent for dexamethasone plus placebo

Both trials were randomized, double blind, placebo-controlled, phase III studies using lenalidomide plus dexamethasone versus dexamethasone plus placebo in previously treated patients with multiple myeloma. An Independent Data Monitoring Committee reviewed the pre-specified interim analysis and found that both Phase III trials met the pre-specified efficacy stopping rule of $p < 0.0015$ for the primary endpoint, time-to-disease progression.

Patients in both lenalidomide trials had been heavily treated prior to enrollment, many having failed three or more rounds of therapy with other agents. In addition, more than 50 percent of patients in the study had undergone stem cell transplantation.

About the International and North American Phase III SPA Trials

Clinical data from the Phase III SPA trials will continue to be accumulated and updated, through patient follow-up, on an ongoing basis. These trials were designed to investigate the effectiveness and safety of cyclic dosing of lenalidomide at 25mg combined with high-dose dexamethasone (HDD) compared with placebo and HDD in previously treated patients with multiple myeloma. These trials enrolled 705 patients and are being conducted in 97 sites internationally. Lenalidomide and HDD are given in 28-day cycles: lenalidomide 25 mg once daily on days 1-21 every 28 days and HDD 40 mg on days 1-4, 9-12 and 17-20 every 28 days. After four cycles the HDD schedule is reduced to 40 mg on days 1-4 every 28 days). The primary endpoint of the study is time-to-disease progression calculated as the time from randomization to the first documentation of progressive disease based on EBMT myeloma response criteria.

In the International trial, patients treated with lenalidomide and dexamethasone had an increase in side effects as compared to patients treated with dexamethasone plus placebo. Grade 3/4 toxicities included neutropenia, thrombocytopenia and anemia. Deep vein thrombosis and pulmonary embolism occurred in 5 percent and 4 percent of patients treated with lenalidomide plus dexamethasone, compared to 5 percent and 1 percent of patients treated with dexamethasone plus placebo.

SAFETY NOTICE:

WARNINGS:

1. POTENTIAL FOR HUMAN BIRTH DEFECTS.

LENALIDOMIDE IS AN ANALOGUE OF THALIDOMIDE. THALIDOMIDE IS A KNOWN HUMAN TERATOGEN THAT CAUSES SEVERE LIFE-THREATENING HUMAN BIRTH DEFECTS. IF LENALIDOMIDE IS TAKEN DURING PREGNANCY, IT MAY CAUSE BIRTH DEFECTS OR DEATH TO AN UNBORN BABY. FEMALES SHOULD BE ADVISED TO AVOID PREGNANCY WHILE TAKING REVLIMID(R) (lenalidomide).

2. HEMATOLOGIC TOXICITY (NEUTROPENIA AND THROMBOCYTOPENIA).

THIS DRUG IS ASSOCIATED WITH SIGNIFICANT NEUTROPENIA AND THROMBOCYTOPENIA IN PATIENTS WITH DEL 5q MDS. EIGHTY PERCENT OF PATIENTS HAD TO HAVE A DOSE DELAY/REDUCTION DURING THE MAJOR STUDY FOR THE DEL 5q MDS INDICATION. THIRTY-FOUR PERCENT OF PATIENTS HAD TO HAVE A SECOND DOSE DELAY/REDUCTION. GRADE 3 OR 4 HEMATOLOGIC TOXICITY WAS SEEN IN 80% OF PATIENTS ENROLLED IN THE STUDY. PATIENTS ON THERAPY SHOULD HAVE THEIR COMPLETE BLOOD COUNTS MONITORED WEEKLY FOR THE FIRST 8 WEEKS OF THERAPY AND AT LEAST MONTHLY THEREAFTER. PATIENTS MAY REQUIRE DOSE INTERRUPTION AND/OR REDUCTION. PATIENTS MAY REQUIRE USE OF BLOOD PRODUCT SUPPORT AND/OR GROWTH FACTORS. (SEE DOSAGE AND ADMINISTRATION)

3. DEEP VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

This drug has demonstrated a significantly increased risk of deep venous thrombosis (DVT) and pulmonary embolism (PE) in patients with multiple myeloma who were treated with REVLIMID(R) (lenalidomide) combination therapy. Patients and physicians are advised to be observant for the signs and symptoms of thromboembolism. Patients should be instructed to seek medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. It is not known whether prophylactic anticoagulation or antiplatelet therapy prescribed in conjunction with REVLIMID(R) (lenalidomide) may lessen the potential for venous thromboembolic events. The decision to take prophylactic measures should be done carefully after an assessment of an individual patient's underlying risk factors.

You can get information about REVLIMID(R) (lenalidomide) on the Internet at <http://www.REVLIMID.com> or by calling the manufacturer's toll-free number at 1-888-423-5436.

IMPORTANT SAFETY INFORMATION

Hypersensitivity: REVLIMID(R) (lenalidomide) is contraindicated in any patients who have demonstrated hypersensitivity to the drug or its components.

Renal impairment: REVLIMID(R) (lenalidomide) is substantially excreted by the kidney, so the risk of toxic reactions may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it would be prudent to monitor renal function.

Nursing mothers: It is not known whether REVLIMID(R) (lenalidomide) is excreted in human milk. Because of the potential for adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

Other adverse events reported in greater than or equal to 15% of del 5q MDS patients: diarrhea (49%), pruritus (42%), rash (36%), fatigue (31%), constipation (24%), nausea (24%), nasopharyngitis (23%), arthralgia (22%), pyrexia (21%), back pain (21%), peripheral edema (20%), cough (20%), dizziness (20%), headache (20%), muscle cramp (18%), dyspnea (17%), and pharyngitis (16%).

About REVLIMID(R)

REVLIMID is a member of a proprietary group of novel immunomodulatory compounds, IMiDs(R). Celgene continues to evaluate REVLIMID in a broad range of hematology and oncology conditions. 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 is approved by the FDA for 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. REVLIMID is not approved by the FDA or any other regulatory agencies as a treatment for any other 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 immuno-globulin 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.

As the second most common blood cancer, multiple myeloma accounts for a reported worldwide prevalence of approximately 200,000 cases. In 2005, there were an estimated 74,000 new cases of multiple myeloma worldwide, and it is estimated that 60,000 people will die from multiple myeloma in 2006.

About Celgene International Sarl

Celgene International Sasrl, located in Neuchatel, Switzerland, is a wholly owned subsidiary and international headquarters of Celgene Corporation. 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 <http://www.celgene.com>.

REVLIMID(R) is a registered trademark of Celgene Corporation.

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.

Web site: <http://www.celgene.com>

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