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**REVLIMID® (Lenalidomide) CLINICAL RESULTS IN NON-HODGKINS  
LYMPHOMA PRESENTED AT THE 11<sup>th</sup> CONGRESS OF THE  
EUROPEAN HEMATOLOGY ASSOCIATION**

Preliminary Phase II Data Demonstrated Response to REVLIMID in Patients with  
Aggressive Non-Hodgkin's Lymphoma

**AMSTERDAM – (June 19, 2006) – Celgene International Sàrl**, a wholly owned subsidiary of Celgene Corporation, announced clinical data from a multi-center, single arm open label Phase II clinical study evaluating single agent lenalidomide in patients with relapsed and refractory aggressive Non-Hodgkins lymphoma (NHL) were presented at the 11<sup>th</sup> Congress of the European Hematology Association (EHA) in Amsterdam, Netherlands on Saturday, June 17, 2006.

NHL is the most common form of blood cancer in the United States affecting more than 360,000 people. Approximately 50 percent have aggressive NHL, while the other half have indolent or follicular lymphoma. According to the American Cancer Society, more than 56,000 men and women in the United States are diagnosed with NHL each year, and 19,000 are expected to die from NHL in 2006.

The data were presented at a poster session by Peter Wiernik, M.D., Director of Clinical Oncology at Our Lady of Mercy Medical Center, Bronx, New York. Preliminary results from Phase II study (NHL-002) with single agent therapy REVLIMID in patients with relapsed and refractory aggressive (NHL) were reported as follows:

- Twenty-five patients age 45-80 (median age 63), with relapsed and refractory aggressive NHL, and who had received a median of 2.5 prior treatments (range: 1-6 prior treatments), were administered 25 mg of REVLIMID orally once daily for 21 days in the treatment cycle.
- Sixteen patients with aggressive NHL were evaluable for tumor assessment, of which there were 5 (31%) patients who experienced objective responses:
  - 1 patient with diffuse large cell lymphoma achieved complete response (unconfirmed) with progression free survival of more than 180 days
  - 1 patient with diffuse large cell lymphoma achieved partial response with progression free survival for 135 days

- 1 patient with diffuse large cell lymphoma achieved partial response with progression free survival for 242 days
- 1 patient with follicular lymphoma achieved partial response with progression free survival for more than 55 days
- 1 patient with mantle cell lymphoma achieved partial response with progression free survival for more than 57 days

### **About the Trial**

The Phase II multi-center, single arm, open label trial was designed to evaluate the therapeutic potential and safety of REVLIMID<sup>®</sup> oral monotherapy in 40 patients with relapsed refractory aggressive NHL following one or more prior treatment regimen with measurable disease. The median number of prior therapies was 2.5 (range: 1-6 prior treatments). Patients in the study received 25 mg of REVLIMID orally once daily for days 1-21 in a 28-day cycle and continued therapy for 52 weeks as tolerated or until disease progression.

As of April 28, 2006, 25 of the 40 patients were enrolled, 22 had received drug and 16 patients were evaluable for response. Of the 16 evaluable patients, 1 patient achieved an unconfirmed complete response (CRu) and 4 patients achieved partial responses (PR) to Revlimid monotherapy. Four patients exhibited stable disease and 7 patients had disease progression after a median follow-up of 2 months (range 1-7 months). Of the 16 patients, 8 had diffuse large cell lymphoma, 3 patients had mantle cell lymphoma, 2 patients had follicular lymphoma, 1 patient had transformed lymphoma, and 2 patients had aggressive lymphoma of unknown histology.

Grade 3 and 4 adverse events occurred in 10 of 22 patients (45%). These were predominately hematological and Grade 3, with only 3 patients (14%) experiencing a Grade 4 adverse reaction.

### **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<sup>®</sup> (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® (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® (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® (lenalidomide) on the Internet at [www.REVLIMID.com](http://www.REVLIMID.com) or by calling the manufacturer's toll-free number at 1-888-423-5436.**

#### **IMPORTANT SAFETY INFORMATION**

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

**Renal impairment: REVLIMID® (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® (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  $\geq 15\%$  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®**

REVLIMID is a member of a proprietary group of novel immunomodulatory compounds, IMiDs®. 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 Non-Hodgkins Lymphoma**

Non-Hodgkin's lymphoma (NHL) is a cancer of B or T cells in the lymph system. NHL encompasses over 29 types of lymphoma and are characterized by the US National Cancer Institute as aggressive (fast growing) and indolent (slow growing). Aggressive lymphomas, also known as intermediate and high-grade lymphomas, tend to grow and spread quickly and cause severe symptoms. Indolent lymphomas, also referred to as low-grade lymphomas, tend to grow quite slowly and cause fewer symptoms.

There are currently more than 360,000 people in the United States living with NHL. Approximately 50 percent have aggressive NHL, while the other half have indolent or follicular lymphoma. According to the American Cancer Society, more than 56,000 men and women in the United States are diagnosed with NHL each year, and 19,000 deaths are attributed to the disease annually.

### **About Celgene International Sàrl**

Celgene International Sàrl, located in Neuchâtel, 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 [www.celgene.com](http://www.celgene.com).

**REVLIMID® 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.*

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