REVLIMID® (Lenalidomide) Approved by the European Commission for the Treatment of Relapsed/Refractory Patients with Mantle Cell Lymphoma

BOUDRY, Switzerland--(BUSINESS WIRE)-- Celgene International Sàrl, a wholly owned subsidiary of Celgene Corporation (NASDAQ: CELG) today announced that the European Commission (EC) has approved REVLIMID® (lenalidomide) for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

MCL is a rare sub-type of aggressive non-Hodgkin's lymphoma (NHL), which starts in the lymph nodes but can move to other organs, causing tumours known as lymphomas. Between 3 and 6 percent of NHL patients have MCL. MCL has the poorest long-term survival of all B-cell lymphoma subtypes, with fewer than 50 percent of patients surviving at 5 years. In Europe there were 93,433 new cases of non-Hodgkin lymphoma, and 37,900 deaths in 2012. MCL has a median age of onset of 70 years and affects men more often than women.

"New treatment options are vitally needed in order to change the course of MCL for patients, given the severity of the disease, and there are still limited existing treatment options," said Prof. Marek Trneny, Charles University in Prague. "Lenalidomide is a proven medicine that has shown efficacy in relapsed/refractory MCL, with the MCL-002 study meeting its primary endpoint of an improvement in progression-free survival (PFS)."

Tuomo Pätsi, President of Celgene in Europe, Middle East and Africa (EMEA), adds: "Today is an important milestone in the fight to find new treatment options for patients with MCL, a difficult-to-treat disease with a high unmet medical need. The approval by the European Commission for REVLIMID® in relapsed/refractory MCL gives us the opportunity to support the needs of patients with MCL. We have a robust clinical program of lymphoma studies reaching patients across the globe with an aim to find new treatment options across numerous types of lymphoma."

The EC decision was based on data from MCL-002, a phase II, multicenter, randomized open-label study to determine the efficacy and safety of REVLIMID® versus the investigator's choice (IC), in 254 patients who were refractory to their last treatment or had relapsed one to three times. In the study, REVLIMID® showed a significant improvement in progression-free survival (PFS) of 8.7 months vs. 5.2 in the control arm (HR = 0.61, p value of .004).

In the study, the most frequently observed adverse reactions which occurred more frequently in the REVLIMID® arm compared with the IC arm were neutropenia (50.9%), anaemia (28.7%), diarrhoea (22.8%), fatigue (21.0%), constipation (17.4%), pyrexia (16.8%), and rash (16.2%).

The EC decision for the use of REVLIMID® in adult patients with relapsed/refractory MCL follows the positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) earlier this year. The EC decision marks the 6th new product or indication granted to Celgene in the last 18 months in the European Union. In 2015, Celgene announced the EC approval of medicines for newly diagnosed multiple myeloma, another form of blood cancer; psoriasis and psoriatic arthritis; a specific subset of acute myeloid leukaemia (AML) patients; and non-small-cell lung cancer (NSCLC).

In addition to the EU approval, REVLIMID® is indicated for the treatment of patients with relapsed/refractory MCL in the United States, Switzerland, Israel, Turkey, Australia, and numerous countries in Latin America. REVLIMID® is also indicated in various countries including the EU for treatment of newly diagnosed and relapsed/refractory multiple myeloma and
myelodysplastic syndromes.

IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY, HEMATOLOGIC TOXICITY, and VENOUS and ARTERIAL THROMBOEMBOLISM

Embryo-Fetal Toxicity

Do not use REVLIMID® during pregnancy. Lenalidomide, a thalidomide analogue, caused limb abnormalities in a developmental monkey study. Thalidomide is a known human teratogen that causes severe life-threatening human birth defects. If lenalidomide is used during pregnancy, it may cause birth defects or embryo-fetal death. In females of reproductive potential, obtain 2 negative pregnancy tests before starting REVLIMID® treatment. Females of reproductive potential must use 2 forms of contraception or continuously abstain from heterosexual sex during and for 4 weeks after REVLIMID® treatment.

Hematologic Toxicity (Neutropenia and Thrombocytopenia)

REVLIMID® can cause significant neutropenia and thrombocytopenia. Eighty percent of patients with del 5q MDS had to have a dose delay/reduction during the major study. 34% 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 for del 5q MDS 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.

Venous and Arterial Thromboembolism

REVLIMID® has demonstrated a significantly increased risk of deep vein thrombosis (DVT) and pulmonary embolism (PE), as well as risk of myocardial infarction and stroke in patients with MM who were treated with REVLIMID® and dexamethasone therapy. Monitor for and advise patients about signs and symptoms of thromboembolism. Advise patients to seek immediate medical care if they develop symptoms such as shortness of breath, chest pain, or arm or leg swelling. Thromboprophylaxis is recommended and the choice of regimen should be based on an assessment of the patient's underlying risks.

About REVLIMID®

REVLIMID® is approved in Europe for the treatment of adult patients with previously untreated multiple myeloma (MM) who are not eligible for transplant. REVLIMID® is also approved in combination with dexamethasone for the treatment of patients with MM who have received at least one prior therapy in nearly 70 countries, encompassing Europe, the Americas, the Middle-East and Asia, and in combination with dexamethasone for the treatment of patients whose disease has progressed after one therapy in Australia and New Zealand.

REVLIMID® is also approved in the United States, Canada, Switzerland, Australia, New Zealand and several Latin American countries, as well as Malaysia and Israel, for transfusion-dependent anaemia due to low- or intermediate-1-risk MDS associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities and in Europe for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with an isolated deletion 5q cytogenetic abnormality when other therapeutic options are insufficient or inadequate.

In addition, REVLIMID® is approved in the United States for the treatment of patients with mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. In Switzerland, REVLIMID is indicated for the treatment of patients with relapsed or refractory MCL after prior therapy that included bortezomib and chemotherapy/rituximab.

About Celgene

Celgene International Sàrl, located in Boudry, in the Canton of 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 www.celgene.com. Follow Celgene on Social Media: @Celgene, Pinterest, LinkedIn and YouTube.
Forward-Looking Statements

This press release contains forward-looking statements, which are generally statements that are not historical facts. Forward-looking statements can be identified by the words “expects,” “anticipates,” “believes,” “intends,” “estimates,” “plans,” “will,” “outlook” and similar expressions. Forward-looking statements are based on management’s current plans, estimates, assumptions and projections, and speak only as of the date they are made. We undertake no obligation to update any forward-looking statement in light of new information or future events, except as otherwise required by law. Forward-looking statements involve inherent risks and uncertainties, most of which are difficult to predict and are generally beyond our control. Actual results or outcomes may differ materially from those implied by the forward-looking statements as a result of the impact of a number of factors, many of which are discussed in more detail in our Annual Report on Form 10-K and our other reports filed with the Securities and Exchange Commission.

All registered trademarks are owned by Celgene Corporation.

###


4 Trneny, M et al. Phase II Randomized, Multicenter Study of Lenalidomide Vs Best Investigator’s Choice in Relapsed/Refractory Mantle Cell Lymphoma: Results of the MCL-002 (SPRINT) Study Blood Dec 2014, 124 (21) 626;


Celgene
Investors:
+41 32 729 8303
[ir@celgene.com](mailto:ir@celgene.com)
or
Media:
+41 32 729 8304
[media@celgene.com](mailto:media@celgene.com)

Source: Celgene

News Provided by Acquire Media