HEALTH CANADA APPROVES REVLIMID® PLUS DEXAMETHASONE AS A FIRST-LINE TREATMENT FOR PATIENTS NEWLY DIAGNOSED WITH MULTIPLE MYELOMA, NOT ELIGIBLE FOR TRANSPLANT

TORONTO, ON (Jan. 24, 2017) - Celgene Inc. announced today that Health Canada has expanded the indication for REVLIMID® (lenalidomide capsules), in multiple myeloma. REVLIMID® in combination with dexamethasone, is indicated for the treatment of multiple myeloma patients who are not eligible for stem cell transplant.[1] Nearly 60 per cent of newly diagnosed people living with multiple myeloma are not eligible for a stem cell transplant,[2] so the expanded indication provides a new option for this patient population, where few existed before.

"The expanded indication of REVLIMID® provides patients with a treatment much earlier in their disease, and offers this patient population an all-oral, melphalan-free option, for a disease that continues to be difficult to treat," said Dr. Donna Reece, Associate Professor of Medicine, Director, Program for Multiple Myeloma and Related Diseases, Princess Margaret Hospital. "We have witnessed the benefits that REVLIMID® has provided patients over the years as an effective and convenient oral medication for relapsing disease. With this new clinical evidence, we know that keeping newly diagnosed multiple myeloma patients on REVLIMID® may help delay disease progression and reduce the risk of death. As such, we are looking forward to having REVLIMID® as a key option in the first-line setting for the appropriate patients."

The indication was expanded based on safety and efficacy results from the phase 3 study, FIRST trial, which evaluated continuous REVLIMID® in combination with dexamethasone until disease progression versus melphalan, prednisone and thalidomide (MPT) for 18 months as the primary analysis.[3] Just over 1,600 newly diagnosed patients who were not candidates for stem cell transplant were studied, including 23 clinical trials sites and 251 patients in Canada, the second highest enrolling country in the world.[4] The median age of trial participants was 73 years old.[5]

"Patients who have been newly diagnosed with multiple myeloma, but who are not eligible for a stem cell transplant, now have the option of REVLIMID®, a convenient once-daily treatment that was previously only available to patients who had relapsed disease," said Aldo Del Col, Co-Founder and Chairman, Myeloma Canada. "I'm pleased to see that some provinces and territories, including Alberta, Saskatchewan, Nova Scotia, the Yukon Territory, New Brunswick and Newfoundland and Labrador, have already included REVLIMID® on their formularies in the first-line setting for these patients, and anticipate that other provinces and territories will soon provide access to patients who may benefit from this treatment."

About Mulitple Myeloma

Myeloma is the third most common blood cancer after lymphoma and leukemia.[6] It is estimated that 2,700 Canadians were diagnosed with multiple myeloma in 2016,[7] and the majority of patients will not be eligible for transplant.[8] Approximately 1,600 men and 1,150 women were diagnosed with multiple myeloma in Canada in 2016.[9] Innovations in treatment have increased the average life expectancy of a myeloma patient, with many living 10 years or longer.[10]

About the FIRST Trial

In this randomized, open-label, three-arm trial, median progression-free survival, the length of time a patient lives from study randomization to disease progression or death, was the primary endpoint of the study. Progression-free survival was significantly longer for patients receiving REVLIMID® Continuous (25.5 months) than for those treated with MPT (21.2 months; HR=0.72; p=0.0001). Median overall survival in the two groups was 58.9 months and 48.5 months, respectively (HR 0.75; 95% CI 0.62, 0.90), based on a March 3, 2014 interim overall survival analysis.[11] Patients in the REVLIMID® Continuous arm had a 25 per cent reduction in the risk of death compared to patients in the MPT arm (HR=0.75).[12]

The most common adverse events reported in the REVLIMID® arm given until disease progression included diarrhea, anemia, constipation, peripheral edema, neutropenia, fatigue, back pain, nausea, asthenia and insomnia.[13]

About REVLIMID®

In Canada, REVLIMID® is already indicated for the treatment of patients with transfusiondependent anemia due to Low- or Intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Approval for this indication is based on red blood cell transfusion independence response rates. Now, REVLIMID® in combination with dexamethasone, is indicated for the treatment of multiple myeloma patients who are not eligible for stem cell transplant.[14]

About Celgene Corporation

Celgene Corporation is an integrated global biopharmaceutical company engaged primarily in the discovery, development and commercialization of novel 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.celgenecanada.net.

Indication and Clinical Use:

REVLIMID® (lenalidomide capsules) in combination with dexamethasone is indicated for the treatment of multiple myeloma patients who are not eligible for stem cell transplant.[15]

Geriatric Patients (>65 years of age): In presence of renal impairment, starting dose adjustments and monitoring of renal function throughout treatment are recommended.

Limitation of Use: REVLIMID® is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia (CLL) outside of controlled clinical trials.

Contraindications:

- Pregnant women and women at risk of becoming pregnant
- Breastfeeding women
- Male patients unable to follow or comply with the required contraceptive measures

Serious Warnings and Precautions:

REVLIMID® should be administered under the supervision of a qualified physician experienced in the use of cancer chemotherapeutic agents.

- **Pregnancy:** Potential for human birth defects, stillbirths, and spontaneous abortions
- **Hematologic:** Neutropenia and thrombocytopenia
- **Venous and arterial thromboembolism:** Deep vein thrombosis (DVT), pulmonary embolism (PE), myocardial infarction (MI) and cerebrovascular events. Antithrombotic prophylaxis recommended.
- **Hepatic**: Hepatotoxicity including fatal cases.

REVLIMID® is only available through a controlled distribution program called RevAid®.

Other Relevant Warnings and Precautions:

- Patients should not donate blood or semen
- Consideration should be given to the dose of dexamethasone used
- Cardiovascular disorders
- Second primary malignancies (SPM)
- Hematologic toxicities
- Hepatotoxicity
- Immune reactions: angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis and graft versus host disease
- Increased mortality in patients with chronic lymphocytic leukemia (CLL)
- Dosage adjustment in moderate or severe renal impairment
- Tumour lysis syndrome in patients with CLL, MM, and non-Hodgkins Lymphoma. Some cases fatal.
- Tumor Flare Reaction in patients with CLL and mantle cell lymphoma (MCL)
- Monitoring and Laboratory testing required
- Lactose/glucose intolerance

For More Information:

Please consult the Product Monograph at www.revlimidpm.ca for important information relating to adverse reactions, drug interactions, and dosing information. The Product Monograph is also available by calling 1-877-923-5436.

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[15] REVLIMID® Product Monograph, December 9, 2016.