Revlimid® (lenalidomide) – New warning

- On September 15, 2017, the FDA approved an update to the *Warnings and Precautions* section of the Revlimid (lenalidomide) drug label regarding early mortality in patients with mantle cell lymphoma (MCL).

- Revlimid is indicated for the treatment of the following:

    - In combination with dexamethasone for the treatment of patients with multiple myeloma (MM).
    - Maintenance therapy in patients with MM following autologous hematopoietic stem cell transplantation (auto-HSCT).
    - 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.
    - Treatment of patients with MCL whose disease has relapsed or progressed after two prior therapies, one of which included Velcade® (bortezomib).

- Revlimid is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia outside of controlled clinical trials.

- Revlimid carries a boxed warning for embryo-fetal toxicity, hematologic toxicity, and venous and arterial thromboembolism.

- In a clinical study, there was an increase in early deaths (within 20 weeks), 12.9% in the Revlimid arm vs. 7.1% in the control arm. On exploratory multivariate analysis, risk factors for early deaths include high tumor burden, MCL international prognostic index score at diagnosis, and high white blood cell at baseline (≥ 10 x 10^9/L).