Revlimid® (lenalidomide) – New indications

- On May 28, 2019, Celgene announced the FDA approval of Revlimid (lenalidomide), in combination with a rituximab (Rituxan®) product for the treatment of adult patients with previously treated follicular lymphoma (FL) and marginal zone lymphoma (MZL).

- Revlimid is also approved for the treatment of adult patients with:

    - Multiple myeloma (MM), in combination with dexamethasone
    - MM, as maintenance following autologous hematopoietic stem cell transplantation
    - Transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities
    - Mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included Velcade® (bortezomib).

- The efficacy of Revlimid with rituximab in patients with relapsed or refractory FL and MZL was evaluated in the AUGMENT and MAGNIFY studies. AUGMENT was a double-blind study in which 358 patients with relapsed or refractory FL and MZL were randomized to Revlimid and rituximab or rituximab and placebo. Efficacy was established based on progression-free survival (PFS). MAGNIFY was an open-label study in which 232 patients with relapsed or refractory FL, MZL, or MCL received 12 induction cycles of Revlimid and rituximab.

    - In AUGMENT, the median PFS was 39.4 months in the Revlimid and rituximab group vs. 14.1 months in the rituximab and placebo group (hazard ratio: 0.46; 95% CI: 0.34, 0.62; $p < 0.0001$).
    - In addition, for the AUGMENT study, 77.5% (95% CI: 70.7, 83.4) of the Revlimid and rituximab group had an objective response vs. 53.3% (95% CI: 45.8, 60.8) of the rituximab and placebo group.
    - In the MAGNIFY study, the overall response was 59% (95% CI: 51, 66) for patients with FL. Median duration of response was not reached with a median follow-up time of 7.9 months (95% CI: 4.6, 9.2).
    - In the MAGNIFY study, the overall response was 51% (95% CI: 36, 66) for patients with MZL. Median duration of response was not reached with a median follow-up time of 11.5 months (95% CI: 8.0, 18.9).

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

- The most common adverse reactions (≥ 15%) with Revlimid use in MCL, FL, and MZL were neutropenia, thrombocytopenia, anemia, leukopenia, diarrhea, constipation, nausea, fatigue, pyrexia, cough, upper respiratory tract infection, and rash.

- The recommended starting dose of Revlimid for FL and MZL is 20 mg orally once daily on days 1 to 21 of repeated 28-day cycles for up to 12 cycles of treatment in combination with a rituximab-product.

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- Refer to the Revlimid drug label for dosing recommendations for rituximab and for all other indications.