Revlimid® (lenalidomide) – Expanded indication

- On February 22, 2017, the FDA approved Celgene's Revlimid (lenalidomide) for multiple myeloma (MM), as maintenance treatment following autologous hematopoietic stem cell transplantation (auto-HSCT).
    - Revlimid is not indicated and is not recommended for the treatment of patients with chronic lymphocytic leukemia outside of controlled clinical trials.
- Revlimid is also approved for MM, in combination with dexamethasone, transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes (MDS) associated with a deletion 5q abnormality with or without additional cytogenetic abnormalities, and mantle cell lymphoma (MCL) whose disease has relapsed or progressed after two prior therapies, one of which included Velcade® (bortezomib).
- Efficacy for the expanded indication of Revlimid was based on two clinical studies enrolling 1,074 MM patients after auto-HSCT to Revlimid maintenance treatment or placebo. The primary efficacy endpoint was progression-free survival (PFS).
    - In study 1, a median PFS was demonstrated for Revlimid maintenance vs. placebo (5.7 years vs. 1.9 years; HR: 0.38 [95% CI: 0.28, 0.50]).
    - In study 2, a median PFS was demonstrated for Revlimid maintenance vs. placebo (3.9 years vs. 2.0 years; HR: 0.53 [95% CI: 0.44, 0.64]).
    - In addition, median overall survival was also demonstrated for Revlimid maintenance vs. placebo (Study 1: 9.3 years vs. 7 years (HR: 0.59 [95% CI: 0.44, 0.78]); Study 2: 8.8 years vs. 7.3 years (HR: 0.90 [95% CI: 0.72, 1.13])).
- Revlimid carries a boxed warning for embryo-fetal toxicity, hematologic toxicity, and venous and arterial thromboembolism.
- The most common adverse events (≥ 20%) with Revlimid use in MM patients were diarrhea, fatigue, anemia, constipation, neutropenia, leukopenia, peripheral edema, insomnia, muscle cramp/spasms, abdominal pain, back pain, nausea, asthenia, pyrexia, upper respiratory tract infection, bronchitis, nasopharyngitis, gastroenteritis, cough, rash, dyspnea, dizziness, decreased appetite, thrombocytopenia, and tremor.
- The recommended dose of Revlimid following auto-HSCT is 10 mg orally once daily (Days 1 - 28 of repeated 28-day cycles) until disease progression or unacceptable toxicity.
    - After 3 cycles of maintenance therapy, the dose may be increased to 15 mg once daily if tolerated.
    - Consult the Revlimid drug label for dosage recommendations for all other indications.