Yervoy® (ipilimumab) – New Indication

- On October 28, 2015, the FDA announced the approval of Bristol-Myers Squibb's Yervoy (ipilimumab), for the adjuvant treatment of patients with cutaneous melanoma with pathologic involvement of regional lymph nodes of more than 1 mm who have undergone complete resection, including total lymphadenectomy.
    - Yervoy is also indicated for the treatment of unresectable or metastatic melanoma.
- Melanoma is the leading cause of death from skin cancer.
    - An estimated 73,870 new cases and 9,940 deaths from the disease have occurred this year according to the National Cancer Institute.
    - Resectable, Stage III melanoma (lymph node > 1 mm) represents about 5% of newly diagnosed melanoma cases annually.
    - Stage III melanoma has about a 60% recurrence after surgery.
- The approval of Yervoy's new indication is based on data from a double-blind, randomized study enrolling 951 patients with Stage III melanoma. The primary endpoint was recurrence-free survival (RFS), a reduction in the risk of recurrence or death.
    - The median RFS was 26 months (95% CI: 19, 39) for Yervoy vs. 17 months (95% CI: 13, 22) for placebo ($p < 0.002$).
- In patients who received Yervoy for this new indication, the most common adverse events (≥ 10%) were rash, diarrhea, fatigue, pruritus, headache, weight loss, nausea, pyrexia, colitis, decreased appetite, vomiting, and insomnia.
- Yervoy carries a boxed warning for immune-mediated adverse reactions.
- The recommended dose of Yervoy for adjuvant melanoma is 10 mg/kg intravenously over 90 minutes every 3 weeks for 4 doses, followed by 10 mg/kg every 12 weeks for up to 3 years or until documented disease recurrence or unacceptable toxicity.
    - The dose for unresectable or metastatic melanoma is 3 mg/kg administered intravenously over 90 minutes every 3 weeks for a total of 4 doses.
- Bristol-Myers Squibb also announced a new patient assistance program in support of the new indication for Yervoy – the Adjuvant Patient Program (APP) for Melanoma.
    - Through the APP Program, Yervoy will be provided free of charge to enrolled patients who have been prescribed Yervoy 10 mg/kg for the adjuvant treatment of fully resected Stage III melanoma (lymph node > 1 mm).