**Generic Name:**
Ipilimumab
**Trade Name:**
Yervoy
**Company:**
Bristol-Myers Squibb
**Notes:**

FDA approved an expanded use of ipilimumab for 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.

Approval was based on improvement in recurrence-free survival (RFS) in a randomized (1:1), double-blind, placebo-controlled trial in 951 patients with resected Stage IIIA (lymph node > 1 mm), IIIB, and IIIC (with no in-transit metastases) histologically confirmed cutaneous melanoma.

The primary efficacy endpoint was RFS determined by an independent review committee. The median RFS was 26 and 17 months in the ipilimumab (n = 475) and placebo (n = 476) arms, respectively (hazard ratio [HR] 0.75 [95% CI 0.64?0.90], *P* <0.002, stratified log-rank test). Safety data were evaluated in 945 patients (median age 51 y; 62% male), who received ipilimumab 10 mg/kg (n = 471) or placebo (n = 474) administered as an I.V. infusion for four doses every 3 weeks, followed by 10 mg/kg every 12 weeks beginning at week 24 up to a maximum of 3 years. Ipilimumab-treated patients received a median of four doses (range: 1?16), and 36% of patients received ipilimumab for longer than 6 months. Ipilimumab was discontinued for adverse reactions in 52% of patients.

The most common adverse reactions included rash, pruritus, diarrhea, nausea, colitis, vomiting, weight loss, fatigue, pyrexia, headache, decreased appetite, and insomnia.

Grades 3?5 immune-mediated adverse reactions, occurring in 41% of ipilimumab-treated patients, included enterocolitis (16%), hepatitis (11%), endocrinopathy (8%), dermatitis (4%), and neuropathy (1.7%). The five treatment-related deaths were due to immune-mediated adverse reactions of enterocolitis (3), Guillain-Barré syndrome (1), and myocarditis (1).

Patients should be assessed for signs and symptoms of enterocolitis, dermatitis, neuropathy, and endocrinopathy and evaluate clinical chemistries, including liver function tests, adrenocorticotropic hormone level, and thyroid function tests, at baseline and before each dose.

The recommended dose and schedule for ipilimumab for adjuvant treatment of melanoma is 10 mg/kg administered intravenously over 90 minutes every 3 weeks for 4 doses followed by 10 mg/kg every 12 weeks for up to 3 years. If toxicity occurs, doses are omitted, not delayed.

**Medication Monitor Categories:**
Supplemental Approvals