FDA Grants Regular Approval to Opdivo for Adjuvant Treatment of Melanoma

Regular approval makes immunotherapy available for more patients with allows advanced melanoma.

December 20, 2017 By Food and Drug Administration (FDA)

On December 20, 2017, the Food and Drug Administration granted regular approval to the anti-PD1 monoclonal antibody, nivolumab (OPDIVO, Bristol-Myers Squibb Company) for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or in patients with metastatic disease who have undergone complete resection. Nivolumab was previously approved for the treatment of patients with unresectable or metastatic melanoma.

Approval was based on improvement in recurrence-free survival (RFS) in a randomized, double-blind trial, CHECKMATE-238 (NCT02388906), in 906 patients with completely resected, Stage IIIB/C or Stage IV (AJCC 7th ed) melanoma. Patients were randomly allocated (1:1) to receive nivolumab 3 mg/kg every 2 weeks or ipilimumab 10 mg/kg every 3 weeks for 4 doses then every 12 weeks beginning at Week 24 for up to 1 year. Enrollment required complete resection of melanoma with margins negative for disease within 12 weeks prior to randomization.

The major efficacy outcome measure was RFS, defined as the time between the randomization date and the date of first recurrence (local, regional, or distant metastasis), new primary melanoma, or death from any cause, whichever occurs first. Patients in the nivolumab arm experienced fewer recurrences/deaths, 34% (n=154), compared with 45.5% (n=206) in the ipilimumab arm (hazard ratio 0.65; 95% confidence interval 0.53, 0.80; $p<0.0001$). Median RFS was not reached on either arm.

The median duration of nivolumab exposure was 11.5 months and 74% of patients received nivolumab for greater than 6 months. Nivolumab was discontinued for adverse reactions in 9% of patients.

The most common adverse reactions (reported in at least 20% of nivolumab-treated patients in CHECKMATE-238) were fatigue, diarrhea, rash, musculoskeletal pain, pruritus, headache, nausea, upper respiratory infection, and abdominal pain. The most common immune-mediated adverse reactions were rash (16%), diarrhea/colitis (6%), and hepatitis (3%).

The recommended dose and schedule of nivolumab in adjuvant melanoma is 240 mg administered as an IV infusion over 60 minutes every two weeks until disease recurrence or unacceptable

toxicity, for a maximum of 1 year.

Full prescribing information is available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125554s055lbl.pdf.

FDA granted priority review to nivolumab for this application and granted the approval approximately eight weeks ahead of the goal date. Nivolumab was granted breakthrough therapy designation for this indication. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics, available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm358301.pdf.

Healthcare professionals should report all serious adverse events suspected to be associated with the use of any medicine and device to FDA's MedWatch Reporting System by completing a form online at http://www.fda.gov/medwatch/report.htm, by faxing (1-800-FDA-0178) or mailing the postage-paid address form provided online, or by telephone (1-800-FDA-1088).

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