FDA Approves Yervoy/Opdivo for MSI-H or dMMR Metastatic Colorectal Cancer

This new use has also been added to the Opdivo label.

July 10, 2018 By Food and Drug Administration (FDA)

FDA grants accelerated approval to ipilimumab for MSI-H or dMMR metastatic colorectal cancer

On July 10, 2018, the Food and Drug Administration granted accelerated approval to ipilimumab (Yervoy, Bristol-Myers Squibb Company Inc.) for use in combination with nivolumab for the treatment of patients 12 years of age and older with microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan.

This new use has also been added to the Opdivo (nivolumab) labeling. Nivolumab received accelerated approval for this indication as a single agent on July 31, 2017.

The approvals were based on data from Study CA209142 (CHECKMATE 142; NCT02060188), a multicenter, non-randomized, multiple parallel-cohort, open-label study that enrolled 82 patients with dMMR or MSI-H mCRC with disease progression during or following fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. Assessment of dMMR or MSI-H tumor status was determined by local laboratories. All patients received ipilimumab 1 mg/kg by intravenous (IV) infusion and nivolumab 3 mg/kg IV every 3 weeks for 4 doses, followed by nivolumab 3 mg/kg IV as a single agent every 2 weeks, until unacceptable toxicity or radiographic progression.

Among these 82 patients, the overall response rate (ORR) as assessed by an independent radiographic review committee using RECIST 1.1 was 46% (95% CI: 35,58), with 3 complete and 35 partial responses, and 89% of responding patients had response durations of ≥6 months. The ORR was higher than that observed in a separate cohort of 58 patients with dMMR/MSI-H mCRC with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy who received nivolumab alone, with an ORR of 28% with 67% having response durations of ≥6 months.

The most common adverse reactions (≥20%) in those receiving ipilimumab and nivolumab are fatigue, diarrhea, pyrexia, musculoskeletal pain, abdominal pain, pruritus, nausea, rash, dyspnea, decreased appetite, and vomiting.

The recommended dosage regimen for this indication is nivolumab 3 mg/kg IV followed by

ipilimumab 1 mg/kg every 3 weeks for 4 doses, then nivolumab 240 mg every 2 weeks.

Efficacy for adolescent patients (12 years and older) with MSI-H or dMMR metastatic CRC is extrapolated from the results in the respective adult population.

View full prescribing information for YERVOY.

View full prescribing information for OPDIVO.

FDA granted ipilimumab and nivolumab breakthrough therapy designations for this indication and granted priority review to these applications. As a condition of accelerated approval, further studies are required to confirm clinical benefit of ipilimumab and nivolumab for this indication. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

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 or by calling 1-800-FDA-1088.

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