

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

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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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