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Nivolumab ± ipilimumab in treatment (tx) of patients (pts) with metastatic colorectal cancer (mCRC) with and without high microsatellite instability (MSI-H): CheckMate-142 interim results.

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**Subcategory:**

Advanced Disease

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**Background:** Evidence supports use of nivolumab (N) in MSI-H mCRC. N, a fully human anti-PD-1 mAb and ipilimumab (I), a humanized anti-CTLA-4 mAb, have favorable safety & efficacy in other tumors. CheckMate-142, a phase 2 study, evaluates N ± I in pts with mCRC, MSI-H and non-MSI-H. **Methods:** Pts had ECOG PS 0–1, and intolerance/progression on ≥ 1 tx. MSI-H pts received N 3 mg/kg q2 wk (N3) or N 3 mg/kg + I 1 mg/kg q3 wk (N3+I1) x 4 doses followed by N3 until disease progression (PD) or other discontinuation. Initial evaluation of N+I at 3 doses was completed in non-MSI-H pts. Primary endpoint was investigator-reported ORR by RECIST 1.1; other endpoints were safety, OS, and PFS. **Results:** 33 (N3) and 26 (N3+I1) MSI-H pts, and 3 (N1+I1), 10 (N1+I3), and 10 (N3+I1) non-MSI-H pts were enrolled. 82% (N3) and 92% (N3+I1) of MSI-H and 100% of non-MSI-H pts had ≥ 2 prior regimens. 15% (N3) and 25% (N3+I1) of MSI-H pts had known BRAF V600E. 17 (52%; N3) and 19 (73%; N3+I1) MSI-H pts remain on tx. Efficacy results are shown in the Table. In MSI-H pts, tx-related adverse events (TRAEs) occurred in 26 (79%; N3) and 22 pts (85%; N3+I1); most common were diarrhea and fatigue (27% each; N3) and diarrhea (46%; N3+I1). Grade 3–4 TRAEs occurred in 7 (N3) and 8 pts (N3+I1). One pt on N3 had a Grade 5 TRAE (sudden death). In non-MSI-H pts median (95% CI) PFS was 1.4 mo (1.2–1.9; pooled N+I). **Conclusions:** N and N+I were well tolerated in most pts and demonstrated encouraging clinical activity and survival in MSI-H mCRC. This study is ongoing. Clinical trial information: [NCT02060188](http://clinicaltrials.gov/show/NCT02060188)

| **MSI-Ha efficacy.** |
| --- |
|  | **N3(n = 33)** | **N3+I1(n = 26)** |
| **ORR, n (%)** | 9 (27) | 4 (15) |
| **CR** | 0 | 0 |
| **Confirmed PR** | 9 (27) | 4 (15) |
| **SD** | 8 (24) | 17 (65) |
| **PD** | 11 (33) | 3 (12) |
| **Not determined/not reported** | 5 (15) | 2 (8) |
| **Median duration of response (95% CI), mo** | NR (4.2–NE) | NR (NE–NE) |
| **Median PFS (95% CI), mo** | 5.3 (1.4–NE) | NR (NE–NE) |
| **4-mo PFS rate,b %** | 55 | 80 |
| **Median OS (95% CI), mo** | 16.3 (8.3–NE) | NR (NE–NE) |
| **5-mo OS rate,c %** | 75 | 100 |

NR, not reached; NE, not estimable aBy local screen bPFS Kaplan-Meier plot estimate, N3 = 17/33 events, N3+I1 = 4/26 events cPFS Kaplan-Meier plot estimate, N3 = 11/33 events, N3+I1 = 0/26 events

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