Nivolumab plus ipilimumab does not show anti-tumor activity in this cohort of patients with microsatellite stable, hTMB colorectal cancer. Other treatment options should be considered for these patients, including treatments offered in clinical trials.

### Results:
- 12 pts enrolled February 2018 to May 2020. 2 pts were not evaluable and excluded from efficacy analysis. Of the 10 evaluable pts, 1 pt had only a baseline visit followed by an SAE due to clinical progression and was not included in Fig 1. TMB ranged from 9-233 Mut/Mb (median 13); for 1 pt Mut/Mb were not specified. Tumor microsatellite (MS) status was stable for 11 pts; indeterminate for 1 pt. PD-L1 status was not tested for 8 pts and negative for 4 pts.
- Demographics: Median age 58 y (range 43, 69); 75% male. Clinical characteristics: 33% PS 0, 67% PS 1; 83% received ≥3 prior systemic regimens; 17% received 2 prior regimens.
- Outcomes: 1 PR (10%) and 0 pts SD>16 (Table 1 and Figure 1). OS and PFS are shown in Table 1 and Figure 2.
- Safety: 4 pts (33%) had ≥1 SAE or Grade 3-4 AE at least possibly related to N+I, including myasthenia gravis, diarrhea, glucose intolerance, hyperglycemia, and small intestinal obstruction.

### Table 1: Efficacy Outcomes (N=10)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Rate (%) (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DC rate</td>
<td>10 (0, 45)</td>
</tr>
<tr>
<td>OR rate</td>
<td>10 (0, 45)</td>
</tr>
<tr>
<td>Median PFS</td>
<td>8.9 (5.1, 16.1)</td>
</tr>
<tr>
<td>Median OS</td>
<td>42.9 (13.0, 57.4)</td>
</tr>
</tbody>
</table>

**Funding supported by Bristol Myers Squibb (BMS). The authors would like to acknowledge the patients who participated in this cohort, as well as the clinical centers and staff.**

**Contact:** TAPURPublications@asco.org

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**Abstract 107: Nivolumab + Ipilimumab in patients with colorectal cancer with high tumor mutational burden (hTMB): Results from the Targeted Agent and Profiling Utilization Registry (TAPUR) Study**

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Nivolumab plus ipilimumab does not show anti-tumor activity in this cohort of patients with microsatellite stable, hTMB colorectal cancer. Other treatment options should be considered for these patients, including treatments offered in clinical trials.

**Background:**
- TAPUR is a phase II basket study that evaluates anti-tumor activity of commercially available targeted agents in patients (pts) with advanced cancers with specific genomic alterations.
- Results of a cohort of pts with colorectal cancer (CRC) with high tumor mutational burden (hTMB), defined as ≥9 mutations/Megabase (Mut/Mb), treated with nivolumab plus ipilimumab (N+I) are reported.

**Methods:**
- **Study Design:**
  - Eligible pts: Advanced CRC, no standard treatment (tx) options, ECOG PS 0-2, adequate organ function, measurable disease. Tx assigned according to pre-specified matching rules based on genomic tests selected by sites.
  - Pts received N at 1 mg/kg IV every 3 weeks for 4 doses in combination with 1 at 3 mg/kg every 3 weeks for 4 doses. N was then continued at 240 mg every 2 weeks or 480 mg every 4 weeks until disease progression.
  - Primary endpoint: Disease control (DC) defined as objective response (OR) or stable disease (SD) at 16+ wks per RECIST v1.1. Secondary endpoints: Progression-free survival (PFS), overall survival (OS), and toxicity per CTCAE. Grade 3-5 adverse events (AEs) or serious adverse events (SAEs) at least possibly related to N+I are reported.

**Results:**
- 12 pts enrolled February 2018 to May 2020. 2 pts were not evaluable and excluded from efficacy analysis. Of the 10 evaluable pts, 1 pt had only a baseline visit followed by an SAE due to clinical progression and was not included in Fig 1. TMB ranged from 9-233 Mut/Mb (median 13); for 1 pt Mut/Mb were not specified. Tumor microsatellite (MS) status was stable for 11 pts; indeterminate for 1 pt. PD-L1 status was not tested for 8 pts and negative for 4 pts.
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