



June 4, 2017

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NCCN Guidelines® Panel: Colon/Rectal/Anal Cancers Panel

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed OPDIVO (nivolumab) clinical data that has been presented at the 2017 American Society of Clinical Oncology (ASCO) Annual Meeting. This phase 2 study evaluated the use of nivolumab plus ipilimumab combination in the treatment of previously treated patients with deficient DNA mismatch repair (dMMR)/high microsatellite instability (MSI-H) metastatic colorectal cancer (mCRC).¹

The use of nivolumab for the treatment of dMMR/MSI-H mCRC is considered investigational.

Rationale: This data is being submitted in response to a standing request from NCCN for new clinical data. The enclosed data presented at ASCO 2017 is from a phase 2 study (CheckMate 142) that evaluated the safety and efficacy of nivolumab plus ipilimumab combination in the treatment of previously treated patients with dMMR/MSI-H mCRC.

The following resources are included for your review.

1. Andre T, et al. Combination of nivolumab (nivo) + ipilimumab (ipi) in the treatment of patients (pts) with deficient DNA mismatch repair (dMMR)/high microsatellite instability (MSI-H) metastatic colorectal cancer (mCRC): CheckMate 142 study. Poster Presentation at the 2017 American Society for Clinical Oncology (ASCO) Annual Meeting June 2-6, 2017; Chicago, IL.
2. Product Information, OPDIVO® (nivolumab) injection for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. April 2017

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Awny Farajallah".

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