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NCCN Guidelines® Panel: Colon/Rectal/Anal Cancers

Dear Panel Members:

On behalf of Bristol-Myers Squibb Company, I respectfully submit to the panel the enclosed prescribing information for OPDIVO® (nivolumab) with an updated indication. With this update, nivolumab is now approved for the treatment of adult and pediatric (12 years and older) patients with mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) metastatic colorectal cancer (mCRC) that has progressed following treatment with a fluoropyrimidine, oxaliplatin and irinotecan. This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.¹

I am also submitting the enclosed OPDIVO® clinical data from the registrational Phase 2 study, CheckMate 142, which was published in *The Lancet Oncology* on July 19, 2017 to the NCCN Colon/Rectal/Anal Cancers Panel for review. This phase 2 study evaluated the use of nivolumab monotherapy in recurrent and metastatic dMMR/MSI-H CRC after prior therapy with fluoropyrimidine and oxaliplatin or irinotecan.²

FDA Clearance: The FDA approved OPDIVO® on July 31, 2017 for the treatment of adult and pediatric (12 years and older) patients with dMMR/MSI-H mCRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin and irinotecan. This indication is approved under accelerated approval based on overall response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.¹

Rationale: This data is being submitted in response to a standing request from NCCN for new clinical data. Data from another cohort of the Phase 2 study, CheckMate 142, was previously submitted to NCCN on June 10, 2017, reflecting the safety and efficacy of nivolumab and ipilimumab combination for the treatment of previously treated dMMR/MSI-H mCRC.

The following resources are included for your review:

1. Product information, OPDIVO® (nivolumab) injection, for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. July 2017.
2. Overman MJ, McDermott JL, Lonardi S, et al. Nivolumab in patients with metastatic DNA mismatch repair-deficient or microsatellite instability-high colorectal cancer (CheckMate142): an open-label, multicentre phase 2 study. *Lancet Oncol.* 2017. [http://dx.doi.org/10.1016/S1470-2045\(17\)30422-9](http://dx.doi.org/10.1016/S1470-2045(17)30422-9)

Thank you for your consideration of this request.

Sincerely,

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