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

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit to the NCCN Colon/Rectal/Anal Cancers Panel the enclosed OPDIVO® (nivolumab) clinical data that has been presented at the 2018 American Society of Clinical Oncology Gastrointestinal Cancers Symposium (ASCO-GI) and published in Journal of Clinical Oncology on January 20, 2018.1,2 This data is from CheckMate 142, a phase 2 study which evaluated the use of nivolumab plus ipilimumab combination in previously treated patients with deficient DNA mismatch repair (dMMR)/high microsatellite instability (MSI-H) metastatic colorectal cancer (mCRC).1

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

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.3

Rationale: This data is being submitted in response to a standing request from NCCN for new clinical data. Preliminary data from the phase 2 study, CheckMate 142, on the use of nivolumab plus ipilimumab combination in previously treated patients with dMMR/MSI-H mCRC was previously submitted to NCCN on June 10, 2017. The enclosed data represents longer follow up of patients in the same study cohort.

The following resources are included for your review.


Thank you for your consideration.

Sincerely,

[Signature]

Vice President, Head US Medical Oncology
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