April 16, 2020
Samantha Gothelf, PharmD
Vice President, US Oncology Medical
Bristol-Myers Squibb Company
3401 Princeton Pike
Lawrence NJ, 08648

NCCN Guidelines® Panel: Neuroendocrine Tumors Panel

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit to the panel the enclosed Opdivo® (nivolumab) plus YERVOY® (ipilimumab) clinical data that was recently published in *Clinical Cancer Research (Clin Cancer Res)*. This information is being submitted for the Panel's consideration.

The SWOG S1609 Dual Anti-CTLA-4 and Anti-PD-1 blockade in Rare Tumors (DART) is a phase 2, prospective, open-label, multicenter trial that evaluated nivolumab plus ipilimumab across multiple rare tumor cohorts. Results from the non-pancreatic neuroendocrine cohort were published.[1]

FDA Clearance: The use of nivolumab plus ipilimumab for patients with neuroendocrine tumors is considered investigational.[2]

Rationale: This data is being submitted in response to a standing request from NCCN for new data.

As part of the submission, the following resources are included for your review:

1. Patel SP, Othus M, Chae YK, et al. A phase II basket trial of dual anti-CTLA-4 and anti-PD-1 blockade in rare tumors (DART SWOG 1609) in patients with non-pancreatic neuroendocrine tumors. *Clin Cancer Res*. 2020. doi: 10.1158/1078-0432.CCR-19-3356. [Epub ahead of print].
2. Product information, OPDIVO® (nivolumab) injection, for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. March 2020.

Thank you for your consideration of this request.

Sincerely,

Samantha Gothelf, PharmD
Vice President, US Oncology Medical
Bristol-Myers Squibb Company