Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab) clinical data that was recently presented at the 2019 European Society for Medical Oncology (ESMO) Congress and simultaneous manuscript which was published in the New England Journal of Medicine on September 28, 2019 to the NCCN Non-Small Cell Lung Cancer Panel for your consideration.

CheckMate 227 is a Phase 3, multi-part, open-label study evaluating nivolumab-based regimens versus platinum-doublet chemotherapy in patients with first-line advanced non-small cell lung cancer across non-squamous and squamous tumor histologies. One of the cohorts, which is Part 1a, evaluated nivolumab plus low-dose ipilimumab or nivolumab monotherapy versus chemotherapy in patients whose tumors express PD-L1. Another cohort, which is Part 1b, evaluated nivolumab plus low-dose ipilimumab or nivolumab plus chemotherapy versus chemotherapy in patients whose tumors do not express PD-L1.1-3

FDA Clearance of OPDIVO® (nivolumab) (indication in non-small cell lung cancer):

- Patients with metastatic non-small cell lung cancer and progression on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving OPDIVO.4

The use of nivolumab with or without ipilimumab as a first-line therapy for patients with non-small cell lung cancer is considered investigational.4-5

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

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


Thank you for your consideration of this request.
Sincerely,

[Signature]

Awny Farajallah, MD, FACP
Vice President, Head US Medical
Bristol-Myers Squibb Company