NCCN Guidelines® Panel: Non-Small Cell Lung Cancer Panel

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed OPDIVO® (nivolumab) in combination with YERVOY® (ipilimumab), OPDIVO® (nivolumab) in combination with platinum-doublet chemotherapy vs platinum-doublet chemotherapy clinical data to the NCCN® Non-Small Cell Lung Cancer Panel for your consideration.

Two presentations at the American Society for Clinical Oncology (ASCO) presented results from CheckMate 227, an open-label, randomized a phase 3 study of first-line nivolumab + ipilimumab, nivolumab monotherapy, or nivolumab + chemotherapy vs chemotherapy in patients with stage IV or recurrent non-small cell lung cancer (NSCLC).1-2

- Borghaei et al presented efficacy and safety results for nivolumab + ipilimumab, nivolumab + platinum-doublet chemotherapy, or platinum-doublet chemotherapy in patients with <1% tumor PD-L1 expression.1
- Reck et al presented safety analysis and patient-reported outcomes for patients receiving nivolumab + ipilimumab vs platinum-doublet chemotherapy.2

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.3

The use of OPDIVO® in combination with YERVOY® or platinum-doublet chemotherapy as a first-line therapy for patients with non-small cell lung cancer is considered investigational.3-4

**Rationale:** These data are being submitted in response to a standing request from NCCN for new clinical data. Please note there was a previous submission to the NCCN NSCLC Panel on April 16, 2018 that included the following data from CheckMate 227 evaluating nivolumab plus ipilimumab as first-line therapy in patients with stage IV NSCLC:

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


Thank you for your consideration.
Sincerely,

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