Dear Panel Members,

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

An oral presentation at the American Association for Cancer Research (AACR) 2018 Annual Meeting and *New England Journal of Medicine* publication presented results from CheckMate 227, an open-label, randomized phase 3 trial that included a co-primary endpoint of progression-free survival (PFS) for nivolumab plus ipilimumab versus platinum doublet chemotherapy as first-line therapy in patients with stage IV or recurrent non-small cell lung cancer (NSCLC) whose tumors have a tumor mutational burden (TMB) of ≥10 mutations/Megabase, regardless of PD-L1 expression.1,3

An additional oral presentation at the AACR 2018 Annual Meeting presented results from CheckMate 568, an open-label, non-randomized, phase 2 trial evaluating nivolumab plus ipilimumab as first-line therapy in patients with stage IV NSCLC.4

**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.5

The use of OPDIVO® in combination with YERVOY® as a first-line therapy for patients with non-small cell lung cancer is considered investigational.5-6

**Rationale:** This data is being submitted in response to a standing request from NCCN for new clinical data. The following resources are included for your review:


Thank you for your consideration.
Sincerely,

Amy Kaelin

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