April 16, 2018

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) 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,

[Signature]

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