Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed clinical data evaluating the neoadjuvant and adjuvant use of OPDIVO® (nivolumab) with or without chemotherapy clinical data to the NCCN® Non-Small Cell Lung Cancer Panel for your consideration.

A presentation at the American Society for Clinical Oncology (ASCO) presented results from the NADIM study, a phase II, single-arm, open-label, multicenter study which evaluated patients with resectable stage IIIA non-small cell lung cancer who received neoadjuvant nivolumab + paclitaxel + carboplatin followed by adjuvant nivolumab.1

A recent publication in the New England Journal of Medicine reported results from a phase 2, single-arm, open-label study evaluating the safety and efficacy of neoadjuvant nivolumab in patients with resectable stage I/II/IIIA NSCLC.2-3

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 OPDIVO® as a neoadjuvant or adjuvant therapy for patients with non-small cell lung cancer is considered investigational.4

Rationale: These data are 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