Panel request to review the data for pembrolizumab as a first-line treatment option for patients with metastatic NSCLC, PD-L1 expression 1-49%, and EGFR, ALK negative or unknown and no contraindications to the addition of pembrolizumab.

External request: Submission from Merck, requesting pembrolizumab monotherapy be recommended as first-line treatment for patients with stage III NSCLC (who are not candidates for surgical resection or definitive chemoradiation) or metastatic non-small cell lung cancer (NSCLC) of any histology whose tumors express PD-L1 with a tumor proportion score (TPS) ≥1% as determined by an FDA-approved test, with no sensitizing EGFR or ALK genomic tumor aberrations as a category 1 in the appropriate sections of the NCCN guidelines, including the section NSCL-E and I.

Based upon review of the data in the noted references, the panel consensus supported the addition of pembrolizumab as a first-line treatment option for patients with metastatic NSCLC, PD-L1 expression 1-49%, and EGFR, ALK negative or unknown and no contraindications to the addition of pembrolizumab. The following footnote was added (NSCL-27): Pembrolizumab monotherapy can be considered in PD-L1 1-49%, in patients with poor PS or other contraindications to combination chemotherapy. The panel consensus supported a category 2B recommendation.

The panel has deferred discussion of the request to add pembrolizumab monotherapy as a first-line treatment option for patients with stage III NSCLC (who are not candidates for surgical resection or definitive chemoradiation) to the annual meeting.

- See Submission for references.