Bristol Myers Squibb™

May 29, 2020

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3401 Princeton Pike
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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) and YERVOY® (ipilimumab) clinical data that were recently presented at the 2020 American Society for Clinical Oncology (ASCO) Annual Meeting. This information is being submitted for the Panel's consideration.

CheckMate 9LA is a Phase 3, randomized, open-label study which evaluated nivolumab in combination with ipilimumab and 2 cycles of platinum-based chemotherapy as a first-line treatment in patients with advanced non-small cell lung cancer across non-squamous and squamous tumor histologies, regardless of PD-L1 expression.[1]

CheckMate 227 is a Phase 3, randomized, multi-part, open-label study which evaluated nivolumab-based regimens versus platinum-doublet chemotherapy as a first-line treatment in patients with advanced non-small cell lung cancer across non-squamous and squamous tumor histologies. One of the cohorts, which is Part 1a, evaluated nivolumab plus low-dose ipilimumab or nivolumab monotherapy versus chemotherapy in patients whose tumors express PD-L1. The co-primary endpoint from Part 1a was overall survival with nivolumab + ipilimumab vs chemotherapy in patients with PD-L1–positive tumors. Another cohort, which is Part 1b, evaluated nivolumab plus low-dose ipilimumab or nivolumab plus chemotherapy versus chemotherapy in patients whose tumors do not express PD-L1. Analyses from Part 1b are descriptive in nature.[2]

FDA Clearance in Non-small Cell Cancer:

OPDIVO® in combination with YERVOY® is indicated for the first-line treatment of adult patients with metastatic NSCLC whose tumors express PD-L1 (≥1%) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.[3,4]

OPDIVO® in combination with YERVOY® and 2 cycles of platinum-doublet chemotherapy is indicated for the first-line treatment of adult patients with metastatic or recurrent NSCLC with no EGFR or ALK genomic tumor aberrations.[3,4]

OPDIVO® monotherapy is indicated for the treatment of patients with metastatic NSCLC with 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]

Rationale: This data is being submitted in response to a standing request from NCCN for new clinical data. Previous submissions to NCCN regarding data from CheckMate 227 Part 1 and new FDA-approved indications based on data from CheckMate 227 Part 1a and CheckMate 9LA were made on September 28, 2019, May 15, 2020 and May 26, 2020, respectively.

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

1. Reck M, Ciuleanu TE, Cobo M, et al. Nivolumab + ipilimumab + 2 cycles of platinum-doublet chemotherapy vs 4 cycles chemo as first-line treatment for stage IV/recurrent NSCLC: CheckMate 9LA. Oral presentation at the 2020 American Society of Clinical Oncology (ASCO) Annual Meeting; May 29-31, 2020; Virtual Meeting.
2. Ramalingam SS, Ciuleanu TE, Pluzanski A, et al. Nivolumab + ipilimumab versus platinum-doublet chemotherapy as first-line treatment for advanced non-small cell lung cancer: Three-year update from CheckMate

227 Part 1. Oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting; May 29-31, 2020; Virtual Meeting.
3. Product Information, OPDIVO® (nivolumab) injection for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. May 2020.
4. Product Information, YERVOY® (ipilimumab) injection for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. May 2020.

Thank you for your consideration of this request.

Sincerely,

Samantha Gothelf, PharmD
Vice President, Head US Medical Oncology
Bristol Myers Squibb Company