



April 11, 2019

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NCCN Guidelines® Panel: Small Cell Lung Cancer Panel

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed clinical data which evaluated the use of nivolumab with or without ipilimumab to the NCCN® Small Cell Lung Cancer Panel for your consideration.

An oral presentation at the 2019 European Lung Cancer Congress (ELCC) presented results on study CheckMate 451, which is a global, double-blind, randomized Phase 3 study, that evaluated the efficacy and safety of nivolumab in combination with ipilimumab and nivolumab monotherapy versus placebo as maintenance therapy in patients with extensive-stage small cell lung cancer without disease progression after completion of first-line platinum-based chemotherapy.¹

FDA Clearance of OPDIVO® (nivolumab) (indication in small cell lung cancer):

- Patients with metastatic small cell lung cancer with progression after platinum-based chemotherapy and at least one other line of therapy.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

All other uses of nivolumab for patients with small cell lung cancer are considered investigational.²

FDA Clearance of YERVOY® (ipilimumab):

The use of ipilimumab for patients with small cell lung cancer is considered investigational.³

Rationale: This data is being submitted in response to a standing request from NCCN for new clinical data.

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

1. Owonikoko TK, Kim HR, Govindan R, Ready N, Reck M, et al. Nivolumab plus ipilimumab, nivolumab, or placebo as maintenance therapy in patients with extensive disease small cell lung cancer after first-line platinum-based chemotherapy: Results from the double-blind, randomized phase 3 CheckMate 451 study. Oral presentation at: the 2019 European Lung Cancer Congress (ELCC); April 10-13, 2019; Geneva, Switzerland.
2. Product Information, OPDIVO® (nivolumab) injection for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. March 2019.
3. Product Information, YERVOY® (ipilimumab) injection for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. July 2018.

Thank you for your consideration.
Sincerely,

A handwritten signature in black ink, appearing to read 'Awny Farajallah', with a stylized flourish at the end.

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