



September 30, 2019

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NCCN Guidelines® Panel: Esophageal and Esophagogastric Junction Cancers

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed Opdivo® (nivolumab) clinical data that was presented at the 2019 European Society for Medical Oncology (ESMO) Annual Congress¹ and simultaneous manuscript, which was published in *Lancet Oncology* on September 30, 2019,² to the NCCN Esophageal and Esophagogastric Junction Cancers Panel for your consideration.

ATTRACTION-3 (ONO-24 / CheckMate 473) is a phase 3, multicenter, randomized, open-label study, which evaluated the use of nivolumab monotherapy for the second-line treatment of patients with unresectable advanced or recurrent esophageal squamous cell carcinoma (ESCC) refractory or intolerant to one prior fluoropyrimidine/platinum-based therapy. Patients received either nivolumab monotherapy or investigator's choice of chemotherapy (docetaxel or paclitaxel) until disease progression or unacceptable toxicity.^{1,2}

The use of nivolumab for the treatment of esophageal squamous cell carcinoma is considered investigational.³

Rationale: These data are being submitted in response to a standing request from NCCN for new data.

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

1. Cho BC, Kato K, Takahashi M, et al. Nivolumab Versus Chemotherapy in Advanced Esophageal Squamous Cell Carcinoma: The ATTRACTION-3 Study. Oral presentation at the European Society for Medical Oncology (ESMO) Annual Congress; September 27 – October 1, 2019; Barcelona, Spain.
2. Kato K, Cho BC, Takahashi M, et al. Nivolumab versus chemotherapy in patients with advanced oesophageal squamous cell carcinoma refractory or intolerant to one prior chemotherapy (ATTRACTION-3): a multicentre, randomised, open-label, phase 3 trial. *Lancet Oncol*; 2019: Published online September 30. DOI: [http://dx.doi.org/10.1016/S1470-2045\(19\)30626-6](http://dx.doi.org/10.1016/S1470-2045(19)30626-6).
3. Product information, OPDIVO® (nivolumab) injection, for intravenous infusion. Bristol-Myers Squibb Company, Princeton, NJ. September 2019.

Thank you for your consideration of this request.

Sincerely,

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