Bristol-Myers Squibb

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NCCN Guidelines® Panel: Hepatobiliary Cancers

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit the enclosed Opdivo® (nivolumab) clinical data, which was recently presented as an oral presentation at the 2019 European Society for Medical Oncology (ESMO) Annual Congress. This information is being submitted for the Panel's consideration.[1]

CheckMate 459 is a phase 3, multicenter, randomized study that evaluated the use of nivolumab monotherapy as first-line treatment in patients with advanced hepatocellular carcinoma. Patients received either nivolumab monotherapy or sorafenib until disease progression or unacceptable toxicity.[1]

FDA Clearance of OPDIVO® (nivolumab) (indication in hepatocellular cancer):

- OPDIVO is indicated as a single-agent for the treatment of patients with advanced HCC who have been previously treated with sorafenib.[2]

The use of nivolumab for patients with advanced HCC in the first-line setting is considered investigational.[2]

Rationale: This data is 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. Yau T, Park JW, Finn RS, et al. CheckMate 459: A Randomized, Multi-Center Phase 3 Study of Nivolumab vs Sorafenib as First-Line Treatment in Patients With Advanced Hepatocellular Carcinoma. Oral presentation at the European Society for Medical Oncology (ESMO) Annual Congress; September 27 – October 1, 2019; Barcelona, Spain.
2. 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