Bristol Myers Squibb™

9/13/2020

Samantha Gothelf, PharmD
Vice President & Head, US Medical Oncology
Bristol Myers Squibb
3401 Princeton Pike
Lawrence NJ, 08648

NCCN Guidelines® Panel: Kidney Cancer Panel

Dear Panel Members,

On behalf of Bristol-Myers Squibb Company, I respectfully submit to the panel the enclosed OPDVO® (nivolumab) clinical data that was recently published as a manuscript in *Clinical Genitourinary Cancer* on August 13, 2020.[1] This information is being submitted for the Panel's consideration.

Checkmate 374 (NCT02596035) is a Phase IIIb/IV prospective, multi-center open-label study designed to evaluate the safety and efficacy of nivolumab monotherapy in a cohort of previously treated patients with advanced non-clear cell renal cell carcinoma.

Specific Changes: I request the Panel to consider listing nivolumab as a Preferred Regimen for the treatment of metastatic renal cell carcinoma, non-clear cell histology (KID-C 2 of 2).

FDA Clearance:

On April 16, 2018, the FDA approved OPDIVO® in combination with YERVOY® for the first-line treatment of previously untreated advanced renal cell carcinoma in patients with intermediate or poor risk renal cell carcinoma. [2]

Additionally, OPDIVO ® is indicated as monotherapy for the treatment of patients with advanced renal cell carcinoma who have received prior antiangiogenic therapy.[2]

The two registrational studies Checkmate 214 and Checkmate 025, which supported the FDA approvals for RCC, required patients to have a histology that had a ccRCC component.

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

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

1. Vogelzang, NJ, Olsen MR, McFarlane JJ et al., Safety and Efficacy of Nivolumab in Patients With Advanced Non–Clear Cell Renal Cell Carcinoma: Results From the Phase IIIb/IV CheckMate 374 Study. Clinical Genitourinary Cancer, 2020.
2. OPDIVO (nivolumab) [package insert]. Princeton, NJ; Bristol-Myers Squibb Company, 2020.

Thank you for your consideration of this request.

Sincerely,

Samantha Gothelf

Samantha Gothelf, PharmD
Vice President & Head, US Medical Oncology