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NCCN Guidelines Panel: Bladder Cancer

Dear NCCN Bladder Cancer Panel Members,

On behalf of the Pfizer and EMD Serono Alliance, we respectfully request the NCCN Guideline Panel for Bladder Cancer to reassess the data of avelumab as first-line maintenance therapy in patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with platinum-containing chemotherapy based on the recent publication of additional peer-reviewed data.

Specific Changes Requested: Consideration for potential upgrading to category 1 from current category 2A recommendation level of avelumab as a first-line maintenance therapy for patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with platinum-containing chemotherapy, based on additional high-level evidence published in peer-reviewed manuscript. This request is for both cisplatin eligible (Preferred regimens) and ineligible patients (Preferred regimens) found on page 42 of NCCN Guidelines Version 6.2020 for Bladder Cancer.

FDA Clearance (Urothelial Carcinoma):

First-Line Maintenance Treatment of Urothelial Carcinoma

Avelumab (BAVENCIO®) is indicated for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy

Rationale: Based on the data from the JAVELIN Bladder 100 trial (NCT02603432), avelumab plus best supportive care (BSC) demonstrated statistically significant improvement in overall survival (OS) compared



with BSC alone in patients with urothelial carcinoma whose disease had not progressed with first-line platinum-based chemotherapy in both the overall population and in patients with PD-L1+ tumors.

The following resources are submitted in support of this requested change:

1. BAVENCIO® (avelumab) prescribing information, EMD Serono, Inc. and Pfizer, Inc., June 2020
2. Powles, T. et al. Avelumab Maintenance Therapy for Advanced or Metastatic Urothelial Carcinoma. N Engl J Med 2020; 383; 13 (Original Article ePub)
3. Powles, T. et al. Avelumab Maintenance Therapy for Advanced or Metastatic Urothelial Carcinoma. N Engl J Med 2020; 383; 13 (Supplementary Appendix ePub)

We greatly appreciate the Panel's thorough consideration for potential upgrading of current recommendation level of avelumab as a first-line maintenance therapy for patients with locally advanced or metastatic bladder cancer (Stage IV) whose disease has not progressed with platinum-based induction chemotherapy.

Best regards,

Constantin and Kirk

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