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NCCN Guidelines Panel: Kidney Cancer

Dear NCCN Guideline Panel for Kidney Cancer:

Request:

Consider the enclosed results from the IMmotion151 study on the use of Tecentriq® (atezolizumab) in patients with previously untreated metastatic renal cell carcinoma (mRCC) published in the *Lancet* on May 9, 2019.¹ IMmotion151 from 2018 American Society of Clinical Oncology Genitourinary Cancers Symposium was previously submitted to NCCN in February 2014, 2018.

Key Takeaways:

IMmotion151 was a Phase III, randomized, controlled trial conducted to evaluate the efficacy and safety of Tecentriq plus bevacizumab vs. sunitinib in patients with previously untreated mRCC with a component of clear cell or sarcomatoid histology. Co-primary endpoints were investigator-assessed progression-free survival (PFS) in the programmed death-ligand 1 (PD-L1) positive population and overall survival (OS) in the intention-to-treat (ITT) population.¹

- After a median follow-up of 15 months in the PD-L1 positive population, the median PFS was 11.2 months in the Tecentriq plus bevacizumab group versus 7.7 months in the sunitinib group (HR 0.74 [95% CI 0.57–0.96]; p=0.0217)
- After median follow-up of 24 months in the ITT population, median OS had an HR of 0.93 (95% CI 0.76–1.14) and the results did not cross the significance boundary at the interim analysis.
- Treatment-related grade 3–4 adverse events occurred in 182 (40%) of 451 patients in the Tecentriq plus bevacizumab group and 240 (54%) of 446 patients in the sunitinib group.
- Treatment-regimen discontinuation due to treatment-related all-grade adverse events occurred in 24 (5%) patients in the Tecentriq plus bevacizumab group and 37 (8%) patients in the sunitinib group.

Of note, a PFS benefit was observed with Tecentriq plus bevacizumab vs. sunitinib in the subgroup analysis of patients with sarcomatoid histology subgroup (Figure 3A).¹ Additional results on the use of Tecent plus bevacizumab vs. sunitinib in patients with previously untreated mRCC and sarcomatoid histology will be presented at ASCO 2019 on Monday, June 3rd.²

FDA Clearance:

- Tecentriq is not FDA-approved for use in patients with previously untreated mRCC.
- Please refer to the Tecentriq prescribing information for the full FDA-approved indications and safety information, available at: https://www.gene.com/download/pdf/tecentriq_prescribing.pdf

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Thank you for your consideration and I hope this information is helpful to you. If you have any questions, please contact us at the phone number and email provided above.

Respectfully submitted,
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References

1. Rini BI, Powels T, Atkina MB, et al. Atezolizumab plus bevacizumab versus sunitinib in patients with previously untreated metastatic renal cell carcinoma (IMmotion151): a multicentre, open-label, phase 3, randomised controlled trial [published online ahead of print May 9, 2019]. *Lancet*. dx.doi.org/10.1016/S0140-6736(19)30723-8. Available at [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(19\)30723-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(19)30723-8/fulltext).
2. Rini, BI, et al. Atezolizumab + bevacizumab versus sunitinib in patients with untreated metastatic renal cell carcinoma and sarcomatoid histology: IMmotion151 subgroup analysis. Available from: 2019 ASCO Annual Meeting iPlanner at <https://iplanner.asco.org/am2019/#/>.