



Submitted by:  
Jordana Wollmann, PharmD  
Managed Care Medical Communications, Medical Affairs  
Genentech, Inc.  
1 DNA Way  
South San Francisco, CA 94080  
Phone: (800) 821-8590  
Email: [genentechmedinfo-d@gene.com](mailto:genentechmedinfo-d@gene.com)  
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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.<sup>1</sup> 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.<sup>1</sup>

- 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).<sup>1</sup> 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 3<sup>rd</sup>.<sup>2</sup>

**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](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,  
Jordana Wollmann, PharmD  
US Medical Affairs, Genentech

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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/#/>.