

Submitted by:
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NCCN Guidelines Panel: Kidney Cancer

Dear NCCN Kidney Cancer Panel :

Please find an enclosed reference for your review regarding Tecentriq® (atezolizumab) and Avastin® (bevacizumab).¹

Request:

Consider the enclosed results from the IMmotion151 study on the use of Tecentriq and Avastin in patients with metastatic renal cell carcinoma (mRCC) presented on February 10th at the 2018 American Society of Clinical Oncology Genitourinary Cancers Symposium.

Rationale:

IMmotion151 is a Phase III, randomized, open-label study conducted to evaluate the efficacy and safety of Tecentriq plus Avastin versus sunitinib in treatment-naïve patients with advanced or metastatic renal cell carcinoma. With a median follow-up of 15 months, the study met its co-primary endpoint of investigator-assessed progression-free survival (PFS) in the programmed death-ligand 1 (PD-L1) positive population. At the time of this analysis, overall survival (OS) data was immature in the intention-to-treat (ITT) population, the other co-primary endpoint. Regarding other pre-specified secondary endpoints, Tecentriq plus Avastin had higher investigator-assessed and independent radiology committee-assessed objective response rates, including complete response, in both PD-L1 and ITT populations as well as time to symptom interference with activities of daily living.

The rate of treatment-related Grade 3-4 adverse events in the Tecentriq and Avastin arm was lower compared to the sunitinib arm (40% vs 54% respectively). The safety profile of Tecentriq in combination with Avastin was consistent with previous clinical studies and no new safety signals were identified.² Please refer to the attached conference proceeding for more detailed efficacy and safety data.

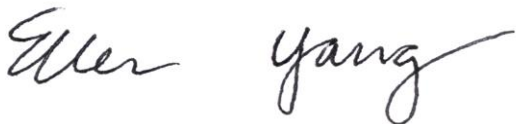
FDA Clearance:

- Tecentriq is not FDA-approved for use in treatment-naïve patients with advanced or metastatic renal cell carcinoma.
- Please refer to the product prescribing information for the full FDA-approved indications and safety information, available at:
 - http://www.gene.com/download/pdf/tecentriq_prescribing.pdf
 - http://www.gene.com/download/pdf/avastin_prescribing.pdf
 -

Any references supplied to you are protected under U.S. Copyright Law (Title 17, U.S. Code). No further reproduction is permitted. Additional data²⁻⁶ on the use of Tecentriq plus Avastin in metastatic renal cell carcinoma are available.

Thank you for your consideration and I hope this information is helpful to you. If you have any questions, please contact me directly.

Respectfully submitted,



Ellen Yang, Pharm.D.

References

1. Motzer B, Powles T, Atkins M, et al. IMmotion151: A Randomized Phase III Study of Atezolizumab Plus Bevacizumab vs Sunitinib in Untreated Metastatic Renal Cell Carcinoma. Presented at the Genitourinary Cancers Symposium of the American Society of Clinical Oncology in San Francisco, CA; February 8–10, 2018. ASCO GU Poster.
2. Genentech Inc. Phase III IMmotion151 study showed Roche's Tecentriq® (atezolizumab) and Avastin® (bevacizumab) reduced the risk of disease worsening or death by 26 percent in certain people with advanced kidney cancer. South San Francisco CA: Genentech Inc, February 6, 2018. <https://www.roche.com/media/store/releases/med-cor-2018-02-06.htm>
3. McDermott D, Atkins M, Motzer R, et al. A Phase II study of atezolizumab with or without bevacizumab vs sunitinib in untreated metastatic renal cell carcinoma patients. Presented at the Genitourinary Cancer Symposium in Orlando, Florida; February 16–18, 2017. ASCO GU Poster #431.
4. McDermott D, Atkins M, Motzer R, et al. A Phase II study of atezolizumab with or without bevacizumab vs sunitinib in untreated metastatic renal cell carcinoma patients. Presented at the Genitourinary Cancer Symposium in Orlando, Florida; February 16–18, 2017. ASCO GU Oral presentation.
5. Powles T, McDermott D, Rini B, et al. IMmotion150: Novel Radiological Endpoints and Updated Data From a Randomized Phase II trial Investigating Atezolizumab With or Without Bevacizumab vs Sunitinib in Untreated Metastatic Renal Cell Carcinoma. Presented at the Congress for the European Society for Medical Oncology in Madrid, Spain; September 8–12, 2017. ESMO Poster #LBA39.
6. Atkins M, McDermott D, Powles T, et al. IMmotion150: a Phase II trial in untreated metastatic renal cell carcinoma patients of atezolizumab and bevacizumab vs and following atezolizumab or sunitinib. Presented at the Annual Meeting of the American Society of Clinical Oncology in Chicago, IL; June 2–6, 2017. ASCO Oral presentation.

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