Genentech
A Member of the Roche Group

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NCCN Guidelines Panel: Bladder Cancer

Dear NCCN Bladder Cancer Panel:

**Request:**
We respectfully request you to consider the inclusion of Tecentriq® (atezolizumab), in combination with carboplatin and etoposide, for the treatment of patients with small cell urothelial carcinoma (SCUC) in the NCCN Guidelines® for Bladder Cancer (page BL-D 1 of 2).

**Rationale:**
SCUC is a rare cancer that is estimated to account for <1% of all bladder cancers.[1-3]

NCCN Guidelines® for Bladder Cancer list the following two chemotherapy regimens as options for the treatment of bladder cancer with any small-cell component in the neoadjuvant and metastatic settings (page BL-D 1 of 2):[4]

- Etoposide + cisplatin
- Etoposide + carboplatin

To support the above chemotherapy options for the treatment of SCUC, NCCN Guidelines® cites clinical trials conducted in patients with small cell lung cancer (SCLC).[4-6] Thus, we respectfully request you to evaluate the results from the IMpower133 trial in Extensive-Stage SCLC for extrapolation of use in patients with SCUC.

IMpower133 was a Phase 3 trial designed to evaluate the use of Tecentriq® (atezolizumab) + carboplatin + etoposide versus placebo + carboplatin + etoposide as first-line treatment for patients with Extensive-Stage SCLC. The trial met both co-primary endpoints of improvement in overall survival (OS) and investigator-assessed progression-free survival (PFS).[7]

- At a median follow-up of 13.9 months, the median OS was 12.3 months in the Tecentriq group and 10.3 months in the placebo group (HR 0.70; 95% CI, 0.54 to 0.91; P=0.007).
- The median PFS was 5.2 months and 4.3 months, respectively (HR for disease progression or death, 0.77; 95% CI, 0.62 to 0.96; P=0.02).
- Adverse events (AEs) occurred in 95% of patients in the Tecentriq group and 92% of patients in the chemotherapy group. Grade 3 or 4 AEs occurred in 57% and 56% respectively, and Grade 5 AEs occurred in 1.5% of patients in each group. Immune-related AEs occurred in 40% of patients in the Tecentriq group and 25% of patients in the placebo group. The safety profile of Tecentriq plus carboplatin and etoposide was consistent with the previously reported safety profile of the individual medicines with no new findings observed.

Please refer to the enclosed publication for full study results.

**FDA Clearance:** [8]

- Tecentriq, in combination with carboplatin and etoposide, is not FDA-approved for the treatment of patients with SCUC. 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

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

**References**

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