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NCCN Guidelines Panel: Small Cell Lung Cancer (SCLC)

Dear NCCN SCLC Panel,

Please find a request for your review regarding NCCN Evidence Blocks™ for Tecentriq® (atezolizumab).

Request(s):
Based on results from the IMpower133 trial, please consider upgrading the NCCN Evidence Blocks™ efficacy of regimen and consistency of evidence ratings for Tecentriq, in combination with carboplatin and etoposide, as first-line therapy in patients with extensive-stage SCLC (ES-SCLC).

- The current efficacy and consistency ratings for Tecentriq plus carboplatin and etoposide are both 3 (out of 5). However, the efficacy and consistency ratings for carboplatin and etoposide are both 4 (out of 5) [Page SCL-E, EB-1].[1] The comparator arm for IMpower133 is the combination of carboplatin and etoposide.

Rationale:
IMpower133, a double-blind, placebo-controlled, Phase 3 trial, was designed to evaluate the efficacy and safety of Tecentriq plus carboplatin and etoposide as first-line treatment for patients with ES-SCLC.

Current NCCN Guidelines for SCLC include Tecentriq, in combination with carboplatin and etoposide, as a Category 1, Preferred Regimen, with the carboplatin and etoposide regimen listed as a Category 2A, Other Recommended Regimen [Page SCL-E 1 of 4].[1]

The trial met both co-primary endpoints of improvement in overall survival (OS) and investigator-assessed progression-free survival (PFS), demonstrating the superior efficacy of Tecentriq, in combination with carboplatin and etoposide, vs. placebo plus carboplatin and etoposide. 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 (hazard ratio for disease progression or death, 0.77; 95% CI, 0.62 to 0.96; P=0.02).[2]

Adverse events (AEs) occurred at similar rates in the Tecentriq and chemotherapy-only groups. Grade 3 or 4 AEs occurred in 57% and 56% in the Tecentriq and chemotherapy groups respectively, and Grade 5 AEs occurred in 1.5% of patients in each 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.[2]

This data has been previously submitted. Please refer to the enclosed publication for full study results.[2]

FDA Clearance:[3]

- Tecentriq, in combination with carboplatin and etoposide, is FDA-approved for the treatment of patients with ES-SCLC.
- 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,
Neda Nguyen, PharmD

References

1. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology. Small Cell Lung Cancer NCCN Evidence Blocks™ Version 2.2020. https://www.nccn.org/professionals/physician_gls/pdf/sclc_blocks.pdf. Accessed December 16, 2019.
2. Horn L, Mansfield A, Szczesna A, et al. Atezolizumab plus Chemotherapy in First-Line Extensive-Stage Small-Cell Lung Cancer. N Engl J Med. 2018 Dec 6;379(23):2220-2229. Available at: https://www.ncbi.nlm.nih.gov/pubmed/30280641. doi: 10.1056/NEJMoa1809064.
3. Tecentriq® [package insert]. South San Francisco, CA: Genentech, Inc.; 2019.