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A Member of the Roche Group

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NCCN Guidelines Panel: Non-Small Cell Lung Cancer

Dear NCCN Guidelines Panel for Non-Small Cell Lung Cancer,

Request:
Please consider for inclusion into the guideline, data from the Phase 3 IMpower110 trial designed to evaluate single-agent Tecentriq® (atezolizumab) for the first-line treatment of PD-L1 selected patients with metastatic non-small cell lung cancer (NSCLC).[1]

Rationale:[1]
IMpower110 was a Phase 3 trial evaluating the efficacy and safety of Tecentriq monotherapy compared with platinum-based chemotherapy as first-line treatment for patients with chemotherapy-naïve, PD-L1-selected, metastatic NSCLC, independent of tumor histology. Patients were randomized 1:1 to either receive Tecentriq (Arm A, n=277) or chemotherapy (Arm B, n=277), followed by maintenance therapy with Tecentriq or supportive care until progressive disease or loss of clinical benefit. The primary endpoint was overall survival (OS) in the Intent-to-Treat (ITT) wild-type (WT) population. After a median follow-up of 15.7 months (range, 0-35 months), the median overall survival in the TC3 or IC3 WT population was 20.2 months in Arm A and 13.1 months in Arm B (HR=0.59; 95% CI, 0.40-0.89; p=0.0106). A summary of the interim OS analysis is shown in Table 1 below.

Table 1: Summary of OS Efficacy Outcomes*

Endpoint	TC3 or IC3 WT		TC2/3 or IC2/3 WT		TC1/2/3 or IC1/2/3 WT	
	Arm A (n=107)	Arm B (n=98)	Arm A: (n=166)	Arm B (n=162)	Arm A (n=277)	Arm B (n=277)
Overall Survival						
Median, mo	20.2	13.1	18.2	14.9	17.5	14.1
HR[a] (95% CI)	0.59 (0.4-0.89); p=0.0106		0.72 (0.52-0.99); p=0.0416[b]		0.83 (0.65-1.07); p=0.1481[c]	
6-mo OS, %	76.3	70.1	79.3	76.1	76.2	75.7
12-mo OS, %	64.9	50.6	60.7	56.0	57.6	54.3

* Data cutoff: September 10, 2018.
[a] Stratified hazard ratio; [b] Criteria for the pre-specified efficacy boundary not crossed; [c] p-value for descriptive purposes only.
HR=hazard ratio; IC=tumor-infiltrating immune cell; NE=not estimable; OS=overall survival; TC=tumor cell.

Grade 3 or 4 AEs occurred in 32% and 54% respectively, and Grade 5 AEs occurred in 4% of patients in each arm. There were fewer AE's leading to treatment withdrawal in patients receiving Tecentriq (6%) versus chemotherapy (16%). All-cause adverse events occurring more frequently with Tecentriq with >5% difference between treatment arms included increased aspartate aminotransferase (AST), pruritus, and hypothyroidism. Tecentriq AE's of special interest requiring use of corticosteroids occurred in 8% of patients in the Tecentriq arm and 0.4% of patients in the chemotherapy arm. Overall, the safety profile of Tecentriq was consistent with prior observations, with no new safety signals identified.

FDA Clearance:[2]

- Tecentriq is not FDA-approved for use as a single agent in chemotherapy-naïve, PD-L1 selected metastatic NSCLC.
- Please refer to the product prescribing information for the full FDA-approved indications and safety information, available at: https://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. Spigel DR, De Marinis F, Giaccone G et al. IMpower110: Interim OS Analysis of a Phase III Study of Atezolizumab (atezo) vs Platinum-Based Chemotherapy (chemo) as 1L Treatment (tx) in PD-L1–selected NSCLC. Presented at the European Society for Medical Oncology (ESMO) 2019 Congress in Barcelona, Spain; Sept 27-Oct 1, 2019. ESMO Abstract #LBA78.
2. Tecentriq® [package insert]. South San Francisco, CA: Genentech, Inc.; 2019