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NCCN Guidelines Panel: Breast Cancer

Dear NCCN Guidelines Breast Panel:

Please find references for your review regarding Tecentriq® (atezolizumab).

Requests:

1. Consider the enclosed IMpassion031 publication to support inclusion of Tecentriq plus nab-paclitaxel for the neoadjuvant treatment of patients with early triple-negative breast cancer (TNBC). [BINV-L; 1 of 6]

Key Takeaways: Tecentriq

IMpassion031 is a Phase 3, double-blind, randomized, multicenter trial that evaluated Tecentriq plus nab-paclitaxel, followed by Tecentriq plus doxorubicin and cyclophosphamide as neoadjuvant treatment in patients with early TNBC.

- IMpassion031 met its co-primary endpoint in the intent-to-treat (ITT) population with a statistically significant improvement in pathological complete response (pCR) in the Tecentriq plus chemotherapy arm vs placebo + chemotherapy arm. Pathological complete response in the Tecentriq plus chemotherapy arm was 57.6% compared to 41.1% in the placebo plus chemotherapy arm (95% CI, 5.9-27.1, p=0.0044). The additional co-primary endpoint of pCR in the programmed death-ligand 1 (PD-L1) positive subpopulation did not show a statistically significant improvement (p-value set at 0.0184) with a pCR of 68.8% vs 49.3%, respectively (95% CI, 4.2-34.8; p=0.021).
- At the time of the primary analysis of pCR, secondary endpoints of event-free survival (EFS), disease-free survival (DFS), and overall survival (OS) were immature. Medians were not reached in either the Tecentriq plus chemotherapy group or the placebo plus chemotherapy group for EFS (HR 0.76, 95% CI 0.40–1.44), DFS (HR 0.74, 95% CI 0.32–1.70), or OS (HR 0.69, 95% CI 0.25–1.87). The IMpassion031 trial was not designed and not powered for secondary time-to-event endpoints.
- The most common treatment-related Grade 3/4 adverse events included neutropenia (23.3% vs 21.6%), decreased neutrophil count (12.2% vs 11.4%), and febrile neutropenia (11% vs 9%) in both the Tecentriq plus chemotherapy arm and the placebo plus chemotherapy arm, respectively. Serious adverse events included febrile neutropenia (9.8% vs 7.8%), pneumonia (3.7% vs 0.6%), and pyrexia (2.4% vs 0%), respectively.

FDA Clearance:

Tecentriq in combination with nab-paclitaxel is currently FDA approved for the treatment of adult patients with metastatic TNBC whose tumors express PD-L1 (tumor-infiltrating immune cell ≥1%), as determined by an FDA-approved test. Tecentriq is not FDA-approved in the early TNBC setting. Please refer to the product prescribing information for the full FDA-approved indications and safety information of Tecentriq, 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,
Ellen Yang, PharmD

References

1. Mittendorf EA, Zhang H, Barrios CH, et al. Neoadjuvant atezolizumab in combination with sequential nab-paclitaxel and anthracycline-based chemotherapy versus placebo and chemotherapy in patients with early-stage triple-negative breast cancer (IMpassion031): a randomised, double-blind, phase 3 trial. Lancet 2020. [ePub ahead of print]. https://pubmed.ncbi.nlm.nih.gov/32966830/