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NCCN Guidelines Panel: Non-Small Cell Lung Cancer Panel

Dear NCCN Non-Small Cell Lung Cancer Panel,

Please find an enclosed reference for your review regarding Tecentriq® (atezolizumab).

Request:

Consider the enclosed information on the use of Tecentriq in patients with previously untreated non-small cell lung cancer (NSCLC) for your drug information updating needs.

Rationale:

IMpower150 was a Phase III, multi-center, open-label, randomized, controlled study evaluating the efficacy and safety of Tecentriq in combination with chemotherapy with or without Avastin in chemotherapy-naïve patients with metastatic non-squamous NSCLC.¹ The trial met two co-primary endpoints of progression-free survival (PFS) in the intention-to-treat (ITT) wild type (WT) and the T-effector-high WT populations. Overall survival in the ITT-WT population, the third co-primary endpoint, has not matured, though preliminary results were reported. The safety profile of Tecentriq and Avastin plus chemotherapy was consistent with known safety risks.

Additional data have been reported on the use of Tecentriq in previously untreated, metastatic non-small cell lung cancer (NSCLC).²⁻⁵

FDA Clearance:

- Tecentriq is not FDA-approved for first line treatment for advanced non-squamous non-small cell lung cancer.⁶
- 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

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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, PharmD.

References

- 1) Reck M, Socinski MA, Cappuzzo F, et al. Primary PFS and safety analyses of a randomized Phase III study of carboplatin plus paclitaxel plus or minus bevacizumab, with or without atezolizumab in 1L non-squamous metastatic NSCLC (IMpower150). Presented at the Immuno Oncology Congress of the European Society For Medical Oncology in Geneva, Switzerland; December 7–10, 2017. ESMO IO Oral presentation #LBA1 PR.
- 2) Peters S, Gettinger S, Johnson ML, et al. Phase II Trial of Atezolizumab As First-Line or Subsequent Therapy for Patients With Programmed Death-Ligand 1-Selected Advanced Non-

Small-Cell Lung Cancer (BIRCH). J Clin Oncol. E-pub Date: [published online ahead of print] June 2017. DOI # [10.1200/JCO.2016.71.9476](https://doi.org/10.1200/JCO.2016.71.9476). <https://www.ncbi.nlm.nih.gov/pubmed/28609226>

- 3) Costa EC, Felip E, Reck M, et al. Updated Efficacy Results From the BIRCH Study: First-Line Atezolizumab Therapy in PD-L1–Selected Patients With Advanced NSCLC. Presented at the International Association For The Study of Lung Cancer 18th World Conference on Lung Cancer in Yokohma, Japan; October 15–18, 2015. IASLC WCLC 2017 Oral Presentation.
- 4) Garassino MC, Rizvi NA, Besse B, et al. Atezolizumab as 1L therapy for advanced NSCLC in PD-L1–selected patients: updated ORR, PFS and OS data from the BIRCH study. Presented at the 17th World Conference on Lung Cancer in Vienna, Austria; December 4–7, 2016. IASLC Oral presentation.
- 5) Spigel DR, Chaft JE, Gettinger SN, et al. Clinical activity and safety from a Phase II study (FIR) of atezolizumab (anti-PDL1) in PD-L1–selected patients with non-small cell lung cancer (NSCLC). Presented at the American Society of Clinical Oncology 2015 Annual Meeting in Chicago, Illinois; May 29–June 2, 2015. ASCO Poster #8028.
- 6) Tecentriq (atezolizumab) [package insert]. Genentech, Inc.; South San Francisco, CA. 2017. https://www.gene.com/download/pdf/tecentriq_prescribing.pdf