



Submitted by:  
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NCCN Guidelines Panel: Malignant Pleural Mesothelioma

Dear NCCN Guidelines Panel:

On behalf of Genentech, Inc., enclosed are results from a Phase II study evaluating Tecentriq® (atezolizumab) in combination with Avastin® (bevacizumab) in patients with relapsed or refractory, unresectable malignant peritoneal mesothelioma (MPeM).

**Request:**

Please consider the inclusion of Tecentriq in combination with Avastin (T+A) as a systemic treatment option for patients with relapsed or refractory and unresectable MPeM.

**Rationale:**

MpEM is an orphan malignancy where no FDA approved therapies are available for patients who progress beyond first-line platinum and pemetrexed-based chemotherapy. In this open-label, single-arm, Phase II study, patients with histologically confirmed MPeM and prior platinum and pemetrexed treatment were treated with 1200 mg of atezolizumab IV and 15 mg/kg of bevacizumab IV until disease progression, unacceptable toxicity, or study withdrawal.

The primary study endpoint was confirmed ORR by RECIST 1.1. DCR, DOR, PFS and OS were pre-specified secondary endpoints.

**Results**

- A total of 20 patients were enrolled with a median age of 63 years. 60% (12/20) were female. 60% (12/20) had an ECOG PS of 0. 40% (8/20) of patients received  $\geq 2$  prior therapies.
- Confirmed ORR by IRF RECIST 1.1 was 40% (8/20 patients; 95% CI: 19.1-63.9). DCR was 85% and median DOR was 10.9 months.
  - 1-year OS was 85% (95% CI: 60-95). Median OS was not reached.
  - Median PFS was 17.6 months (95% CI: 9.1 – NR). 1-year PFS was 61% (95% CI: 35-80)
  - Response to the combination of T+A occurred in the absence of dMMR or high TMB and in PD-L1 positive and negative tumors
- The most common AEs were hypertension and proteinuria (55% and 30%, respectively). Grade 3 treatment-emergent adverse events (AEs) occurred in 10/20 patients, with 2 patients experiencing Grade 3 immune-related AEs. There were no Grade 4 or 5 treatment related AEs.

**FDA Clearance:**

- Tecentriq and Avastin are not FDA-approved for the treatment of MPeM. Please refer to the product prescribing information for the full FDA-approved indications and safety information of Tecentriq and Avastin, available at:
  - <https://www.gene.com/medical-professionals/medicines/tecentriq>
  - <https://www.gene.com/medical-professionals/medicines/avastin>



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We appreciate your review and consideration.

Sincerely,  
Patrice Esser, PharmD, MPH

**References:**

1. KPS Raghav, Overman MJ, Liu S, et al. A phase II trial of atezolizumab and bevacizumab in patients with relapsed/refractory and unresectable malignant peritoneal mesothelioma. Presented at the American Society of Clinical Oncology (ASCO) Annual Virtual Meeting 2020. DOI: 10.1200/JCO.2020.38.15\_suppl.9013 Journal of Clinical Oncology 38, no. 15\_suppl (May 20, 2020) 9013-9013.