Dear NCCN Guidelines Panel:

On behalf of Genentech, Inc., please find updated data from the Phase 1b GO30140 study enclosed for your review.¹²

**Request:**

Consider the inclusion of Tecentriq® (atezolizumab) and Avastin® (bevacizumab) as an initial first-line treatment for patients with previously untreated, unresectable hepatocellular carcinoma (HCC).

**Rationale:**

Data reported from the GO30140 study continue to demonstrate the activity of Tecentriq and Avastin in patients with previously untreated, unresectable HCC.¹²

**Arm A:**¹

- In 104 patients with unresectable HCC and Child-Pugh score of up to B7, treatment with Tecentriq and Avastin resulted in an ORR of 36%, CR of 12%, and DCR of 71%. Responses were observed in all assessed patient subgroups, including patients with high-risk disease. At baseline, 88% of patients had extrahepatic spread and/or macroscopic vascular invasion.
- Median PFS was 7.3 months (95% CI 5.4–9.9). Responses were durable with 54% of patients showing responses ≥ 9 months and 30% ≥ 12 months. 76% of patients had an ongoing response at time of analysis.
- The primary endpoint for Arm A was ORR per IRF-assessed RECIST 1.1 with a median duration of follow up of 12.4 months.

**Arm F:**²

- A total of 119 patients were randomized to receive either Tecentriq and Avastin combination or Tecentriq monotherapy.
- Data from Arm F demonstrate the superiority of the combination of Tecentriq and Avastin over Tecentriq monotherapy with a median PFS of 5.6 months vs 3.4 months [HR of 0.55 (80% CI 0.40–0.74), p=0.0108].
- The primary endpoint for Arm F was PFS per IRF RECIST 1.1 with a median duration of follow up of 6.6 months.

In both arms, the combination of Tecentriq and Avastin was generally well tolerated and toxicities were manageable.¹²

- The safety profile of Tecentriq and Avastin was consistent with previously reported safety risks of the individual medicines.¹²
- Arm A: Grade 3-4 treatment related adverse events were noted in 39% of the study population. Ten percent of AEs lead to study withdrawal.¹
Arm F: Grade 3-4 treatment related adverse events were noted in 20% of patients treated with Tecentriq and Avastin and 5% of patients treated with Tecentriq monotherapy. Three percent of AEs lead to study withdrawal in patients treated with Tecentriq and Avastin and 2% in patients treated with Tecentriq monotherapy.²

**FDA Clearance:**

The U.S. Food and Drug Administration granted Breakthrough Therapy Designation for Tecentriq in combination with Avastin as first-line treatment for patients with advanced or metastatic HCC.³

- Tecentriq and Avastin are not FDA-approved for the treatment of HCC. Please refer to the product prescribing information for the full FDA-approved indications and safety information of Tecentriq and Avastin, available at:

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Thank you for your consideration. If you have any questions, please contact us at the phone number and email provided above.

Respectfully submitted,
Patrice Esser, PharmD, MPH

**References:**