



Submitted by:
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Date of request: October 30, 2018
NCCN Guidelines Panel: Hepatobiliary Cancers

Dear NCCN Guidelines Panel:

On behalf of Genentech, Inc., please find data from the GO30140 study enclosed for your review. This study evaluated the combination of Tecentriq® (atezolizumab) and Avastin® (bevacizumab) for the treatment of advanced or metastatic hepatocellular carcinoma (HCC).¹

Request:

Please consider the inclusion of Tecentriq and Avastin as an initial first-line systemic treatment for patients with advanced or metastatic HCC.

Rationale:

Patients with advanced HCC continue to have limited treatment options. Data from the GO30140 study demonstrate activity of Tecentriq and Avastin in this patient population.¹

- In patients with unresectable or advanced HCC (n=73), treatment with Tecentriq plus Avastin resulted in an ORR of 32% per INV-assessed RECIST and 34% per IRF-assessed HCC mRECIST. Responses were observed in all assessed patient subgroups, including etiology, region, baseline alpha-fetoprotein levels and tumor burden.
- Responses were durable with 52% of patients having responses lasting ≥ 6 months and 26% lasting for ≥ 12 months.
- The safety profile of Tecentriq and Avastin was consistent with previously reported safety risks of the individual medicines.

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.²

- Tecentriq is 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:
 - <https://www.gene.com/medical-professionals/medicines/tecentriq>
 - <https://www.gene.com/medical-professionals/medicines/avastin>

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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:

1. Michael J. Pishvaian, Michael S. Lee, Baek-Yeol Ryoo, et al. Phase 1b Study of Atezolizumab + bevacizumab in HCC-update on safety and clinical activity. Presented at the European Society for Medical Oncology (ESMO) Conference in Munich, Germany; October 19–23, 2018. ESMO Presentation #LBA26.
2. Genentech, Inc. (2018, July 17). *FDA Grants Breakthrough Therapy Designation for Genentech's TECENTRIQ in Combination With Avastin as First-Line Treatment for Advanced or Metastatic Hepatocellular Carcinoma (HCC)* [Press release]. Retrieved from <https://www.gene.com/media/press-releases/14736/2018-07-17/fda-grants-breakthrough-therapy-designat>