Patients with HBV, HCV, or Both in the IMbrave150 Trial

This article responds to your request for information on the use of Tecentriq® (atezolizumab) in patients with hepatitis B (HBV), or hepatitis C (HCV), or both. This article contains data from published and unpublished sources.

In Brief

- The Phase 3 IMbrave150 trial assessed the use of first-line Tecentriq in combination with Avastin versus sorafenib in patients with locally advanced or metastatic unresectable HCC.
- HBV and HCV infection levels in patients were assessed at trial enrolment:
    - Patients were excluded from the IMbrave150 trial if they had both active HBV and active HCV.
    - Patients with active, controlled HBV were included in the trial, if HBV was treated and HBV DNA <500 IU/mL within 28 days of trial initiation.
    - Patients with active, controlled HCV infection were included in the trial.
    - Nucleoside / nucleotide analogues and antivirals were used in IMbrave150 to treat HBV and HCV in the trial.

Abbreviations

HBV= Hepatitis B virus

HCV= Hepatitis C virus

HCC= Hepatocellular carcinoma

PCR= Polymerase chain reaction

IMBrave150 trial overview

IMbrave150 was a Phase 3, global, open-label, randomised study that evaluated the efficacy and safety of Tecentriq in combination with Avastin, versus sorafenib in 501 patients with locally advanced or metastatic unresectable HCC[1].

Eligible patients had to have

- no prior systemic therapy,
- Child-Pugh A liver cirrhosis,
- performance status of 0 or 1, and
- measurable disease per RECIST v1.1 not amendable to curative or locoregional therapies.

The IMBrave150 protocol provides a full list of additional inclusion and exclusion criteria[1].

Inclusion and exclusion criteria according to HBV and HCV status

Levels of HBV and HCV infection were assessed in patients at trial enrolment. Table 1 provides the inclusion and exclusion criteria for patients with HBV and HCV infection in the IMbrave150 trial.

Table 1. Inclusion and exclusion criteria in the IMbrave150 trial for patients wtih active HBV or HCV[1]

If patients had...	Then they were...	On the condition that...
active HBV	included in trial	• HBV DNA was <500 IU/mL within 28 days prior to initiation of study treatment, and • anti-HBV treatment (per local standard of care; e.g., entecavir) was provided for a minimum of 14 days prior to study entry. Patients had to be willing to continue treatment for the length of the study.
active HCV*		HCV infection was controlled.
both active HBV and active HCV*	excluded from the trial.	
* Patients who had a history of HCV infection, but were negative for HCV RNA by PCR, were considered non-infective with HCV.		

Patient characteristics at baseline

Table 2 provides data on the number of patients in the IMbrave150 trial who had HBV and HCV infection at baseline. As Table 1 shows, patients were not enroled to the trial if they had co-infection with both active HBV and active HCV.

Table 2. Number of patients with HBV and HCV infections in the IMbrave150 trial[2]

Infection at baseline	Tecentriq and Avastin (n=336) n (%)	Sorafenib (n=165) n (%)
HBV	97 (29.5)	35 (22.4)
Chronic HBV	36 (10.9)	23 (14.7)
HCV	34 (10.3)	20 (12.8)
Chronic HCV	10 (3.0)	8 (5.1)

HBV and HCV medication

Table 3 provides data on the HBV and HCV medication administered to patients in the IMbrave150 trial.

Table 3. Patients receiving treatment for hepatitis in the IMbrave150 trial[2]

Previous or concomitant medication	Tecentriq and Avastin (n=336) n (%)	Sorafenib (n=165) n (%)
Nucleoside / nucleotide analogues (including entecavir, tenofovir, tenofovir disoproxil fumerate)	132 (40.1)	53 (34.0)
Anti-virals (including sofosbuvir, ledipasvir and ribovarin)	22 (6.7)	7 (4.5)

Efficacy and safety stratified by HBV and HCV status

Subgroup analyses of IMbrave150 safety and efficacy data for HBV and HCV patients was not performed[2].

References

1. Finn R, Qin S, Ikeda M, et al. Atezolizumab plus Bevacizumab in Unresectable Hepatocellular Carcinoma. N Engl J Med 2020;382:1894-1905. https://www.ncbi.nlm.nih.gov/pubmed/32402160

2. Roche Internal Clinical Study Report (Accessed July 2023).