# AdvanTIG-206: Anti-TIGIT monoclonal antibody ociperlimab + anti-PD-1 monoclonal antibody tislelizumab + BAT1706 vs tislelizumab + BAT1706 as first-line treatment for unresectable hepatocellular carcinoma

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## Conclusions

**AdvanTIG-206 is a Phase 2 study designed to investigate the efficacy and safety of ociperlimab in combination with tislelizumab plus BAT1706, and of tislelizumab plus BAT1706, as first-line treatments in patients with unresectable HCC.**

## Background

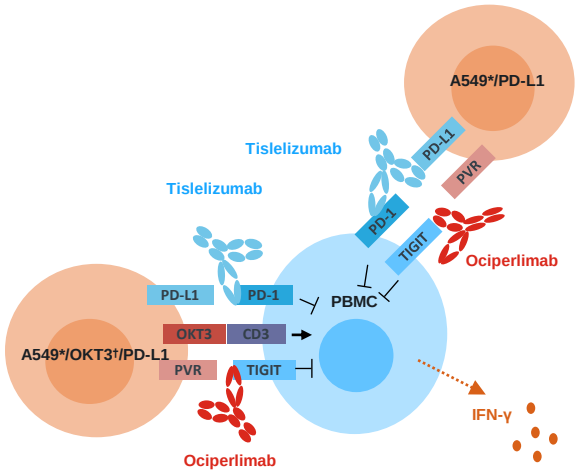
Liver cancer is one of the leading causes of cancer-related mortality, with 841,000 new cases reported in 2018.[1] Tyrosine kinase inhibitors (sorafenib and lenvatinib) are approved in first-line treatment for unresectable hepatocellular carcinoma (HCC); however, life expectancy remains poor.[2–6]

In the first-line setting, the combination of anti-programmed death-ligand 1 (PD-L1) therapy with anti-vascular endothelial growth factor (VEGF) therapy has improved overall survival and progression-free survival outcomes compared with sorafenib for patients with unresectable HCC.[7]

Despite improvements in clinical outcomes with PD-L1 combination therapy, new treatment options are needed to further improve overall survival and quality of life for patients with unresectable HCC.

Dual targeting of tumors with anti-T cell immunoreceptor with immunoglobulin and immunoreceptor tyrosine-based inhibitory motif domain (TIGIT) and anti-programmed cell death protein 1 (PD-1) mAbs (**Figure 1**) has shown synergistic inhibition of liver cancer growth in preclinical studies.[8] Furthermore, BAT1706 is a proposed biosimilar of the anti-VEGF antibody, bevacizumab, that has been shown to improve survival rates in HCC.[9]

### Figure 1. Dual targeting with anti-TIGIT and anti-PD-1 antibodies



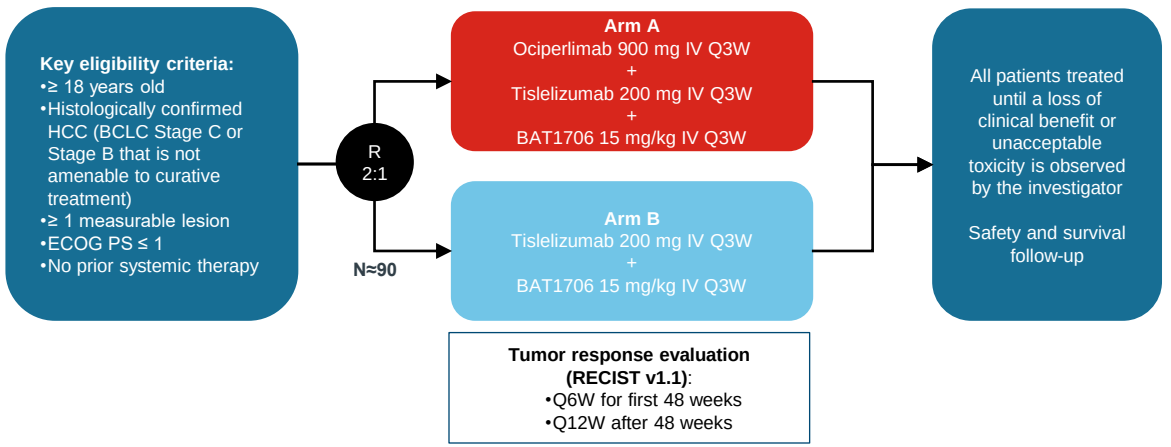

*Chen X, et al. Data presented at AACR 2021 (Abs 1854)[10]*
**PVR positive A549 cells; †anti-CD3 antibody clone. IFN, interferon; PBMC, human peripheral blood mononuclear cells; PD-1, programmed cell death protein 1; PD-L1, programmed death-ligand 1; PVR, poliovirus receptor; TIGIT, T cell immunoreceptor with immunoglobulin and immunoreceptor tyrosine-based inhibitory motif domain*

## Methods

AdvanTIG-206 is a randomized, multicenter, open-label, Phase 2 study (NCT04948697).

Approximately 90 patients aged ≥ 18 years with histologically confirmed unresectable HCC, not amenable to curative treatment, will be enrolled (**Figure 2**).

### Figure 2. AdvanTIG-206 study design




*BCLC, Barcelona-Clinic Liver Cancer; ECOG PS, Eastern Cooperative Oncology Group performance status; HCC, hepatocellular carcinoma; IV, intravenous; Q3W, every 3 weeks; Q6W, every 6 weeks; Q12W, every 12 weeks; R, randomized; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1*

### Endpoints and assessments

The primary endpoint is objective response rate as assessed by the investigator according to Response Evaluation Criteria in Solid Tumors version 1.1 (**Table 1**).

**Table 1. AdvanTIG-206 endpoints**

| | |
|---|---|
| **Primary endpoint** | •INV-assessed ORR per RECIST v1.1 |
| **Secondary endpoints** | •INV-assessed DoR, TTR, DCR, CBR, and PFS<br>•OS<br>•Safety and tolerability<br>•Serum concentrations of ociperlimab, tislelizumab, and BAT1706 at specified timepoints<br>•Immunogenic responses to ociperlimab, tislelizumab, and BAT1706 evaluated through detection of ADAs |
| **Exploratory endpoint** | •Potential biomarkers associated with clinical response/resistance to study treatments |

*ADA, antidrug antibody; CBR, clinical benefit rate; DCR, disease control rate; DoR, duration of response; INV, investigator; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; RECIST v1.1; Response Evaluation Criteria in Solid Tumors version 1.1; TTR, time to response*

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