

## Immunotherapy might work in bile duct cancer after all



Jacob Plieth

Imfinzi's apparent hit today in Topaz-1, a pivotal first-line cholangiocarcinoma trial, is an unexpected success. Treating this rare malignancy, also known as bile duct cancer, has only recently seen progress, but this came thanks to targeted treatments like Incyte's Pemazyre and Bridgebio's Truseltiq. Meanwhile, immuno-oncology has fired blanks, including an early, academic-sponsored trial of Bristol Myers Squibb's Opdivo [yielding "modest" efficacy](#), and Merck KGaA's fusion protein [bintrafusp alfa failing to hit a remission rate threshold](#). Perhaps because of the setbacks, and the small market, pharma activity with PD-(L)1 inhibitors is modest here. But Astra's success should be of interest to Merck & Co, whose Keynote-966 study of Keytruda has a similar design to Topaz-1. Roche is running Imbrave-151, combining Tecentriq plus chemo with or without Avastin in first-line disease, but this did not appear on the Swiss group's latest summary of clinical trials. While Astra says Imfinzi plus chemo beat chemo alone in Topaz-1, yielding a statistically significant and clinically meaningful overall survival benefit, full data are being kept back for a medical meeting. Gauging the importance of patients' PD-L1 positivity will be especially key to determining the extent of immunotherapy's potential in this cancer type.

### Advanced studies of anti-PD-(L)1 MAbs in cholangiocarcinoma

Study	Drug (company)	Design	Primary endpoint
<a href="#">Topaz-1</a>	Imfinzi (Astrazeneca)	1st-line, chemo combo	OS vs chemo alone
<a href="#">Keynote-966</a>	Keytruda (Merck & Co)	1st-line, chemo combo	OS vs chemo alone
<a href="#">Imbrave-151*</a>	Tecentriq (Roche)	1st-line, chemo combo +/- Avastin	PFS vs chemo alone
<a href="#">KN035-BTC (China trial)</a>	Enfavalimab (3D Medicines)	1st-line, chemo combo	OS vs chemo alone
<a href="#">NCT03796429 (China trial)*</a>	Toripalimab (Shanghai Junshi)	1st-line, chemo combo	PFS & OS (no comparator)

Note: \*ph2 trial, others are ph3. Source: [clinicaltrials.gov](#) & medical papers.

[More from Evaluate Vantage](#)

Evaluate HQ  
[44-\(0\)20-7377-0800](tel:+14152073770)

Evaluate Americas  
[+1-617-573-9450](tel:+16175739450)

Evaluate APAC  
[+81-\(0\)80-1164-4754](tel:+8108011644754)

© Copyright 2022 Evaluate Ltd.