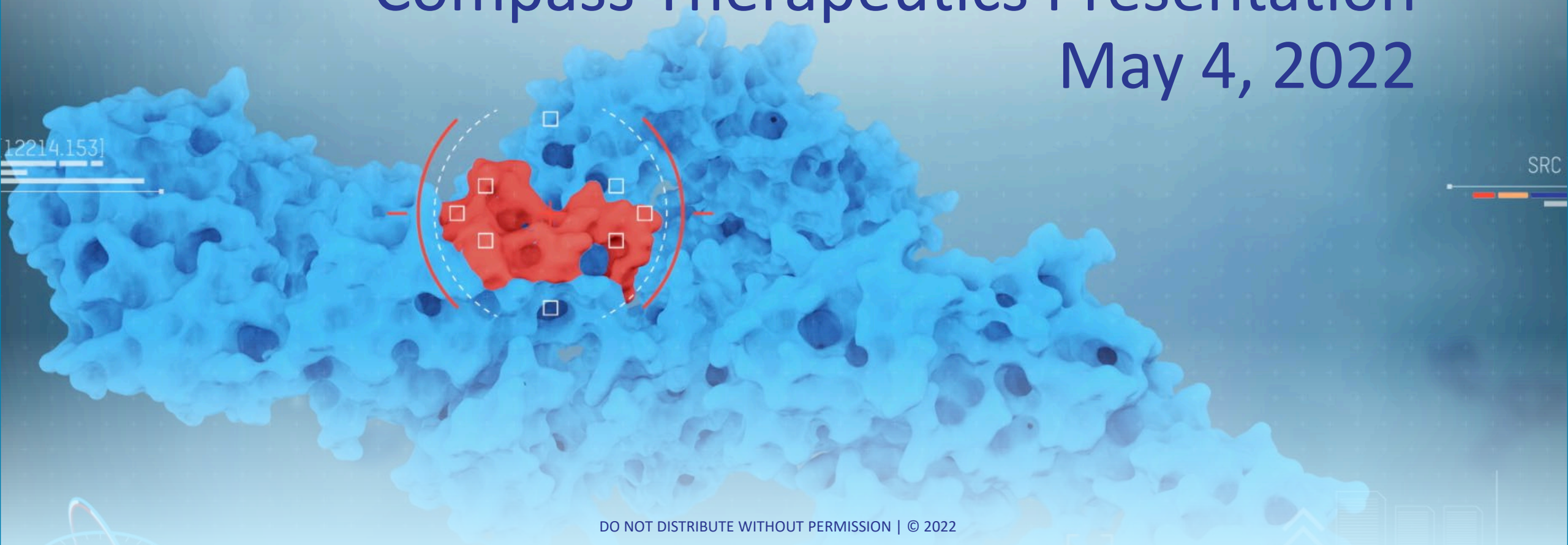
COMPASS THERAPEUTICS

Compass Therapeutics Presentation
May 4, 2022



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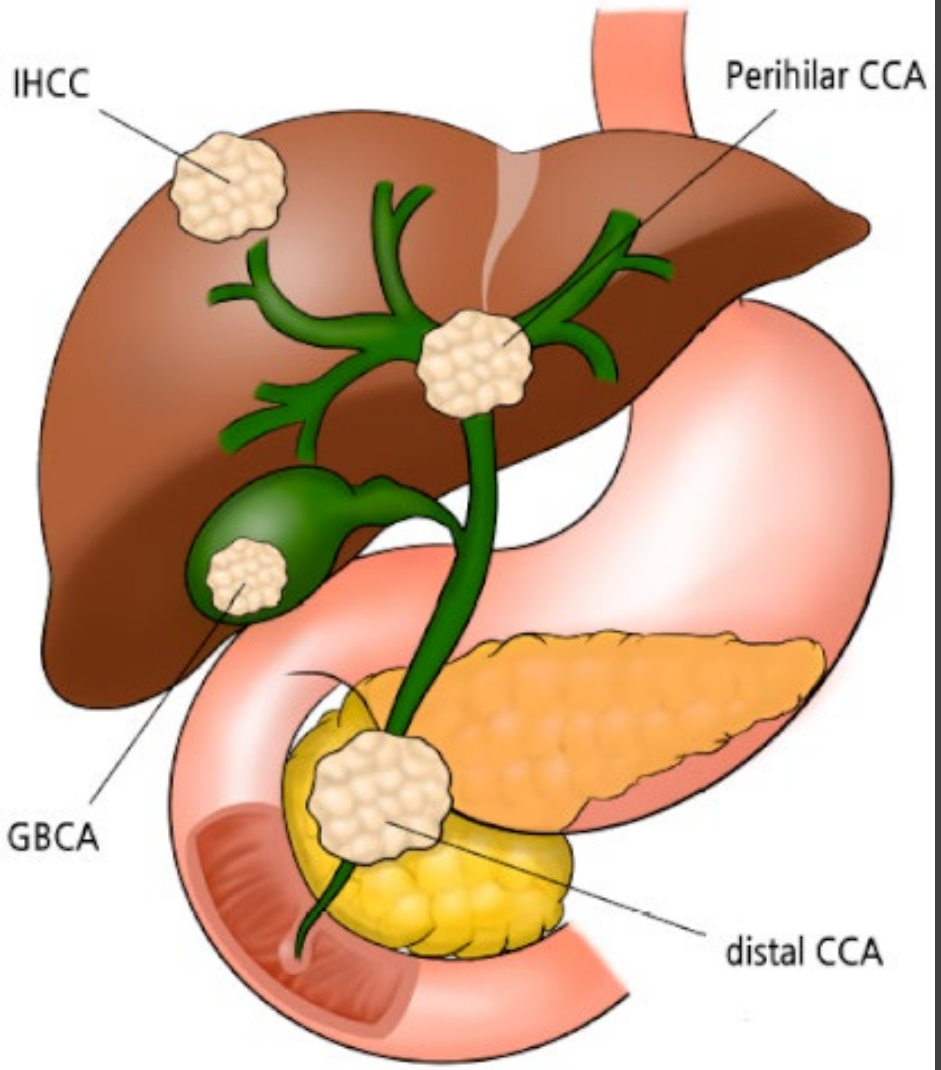
Advanced Biliary Track Cancers (BTC)

Richard M. Goldberg MD
Professor and Director Emeritus
The West Virginia University Cancer Institute



Subtypes of BTC

- Gallbladder cancer (GBCA),
- Cholangiocarcinoma
  - intrahepatic [IHCC],
  - Perihilar [PCCA],
  - Extrahepatic [ECC]
- Ampulla of Vater cancer (AVC)

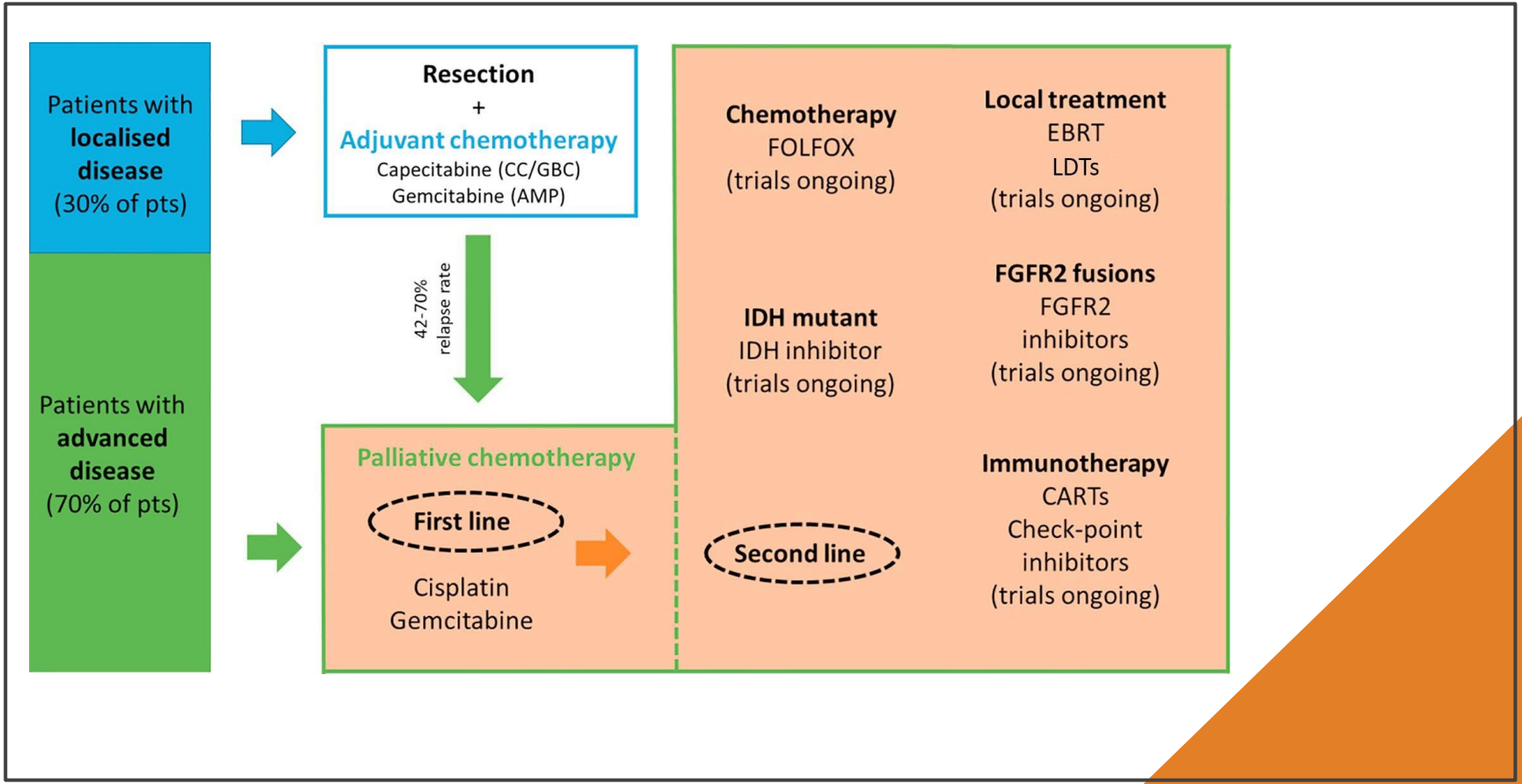
BTC Epidemiology, 2021

	US	Worldwide
Cases	18,300	210,887
Deaths	11,310 (62%)	173,974 (84%)

- Lifetime risk: Highest in Chile and Asian countries
- 76% Increase in incidence over last 2 decades
- Risk factors: Inherited, liver flukes, chronic liver or biliary inflammation, obesity, tobacco use

Presentation

- Jaundice, yellow eyes, itching, dark urine, light colored stool
- Loss of appetite and weight loss
- Abdominal pain
- Night sweats
- Found incidentally at the time of gall bladder surgery


Patients with localised disease (30% of pts)
Patients with advanced disease (70% of pts)
Resection
+
Adjuvant chemotherapy
Capecitabine (CC/GBC)
Gemcitabine (AMP)
42-70% relapse rate
Palliative chemotherapy
First line
Cisplatin
Gemcitabine
Second line
Chemotherapy
FOLFOX
(trials ongoing)
IDH mutant
IDH inhibitor
(trials ongoing)
Local treatment
EBRT
LDTs
(trials ongoing)
FGFR2 fusions
FGFR2
inhibitors
(trials ongoing)
Immunotherapy
CARTs
Check-point
inhibitors
(trials ongoing)

Original Article

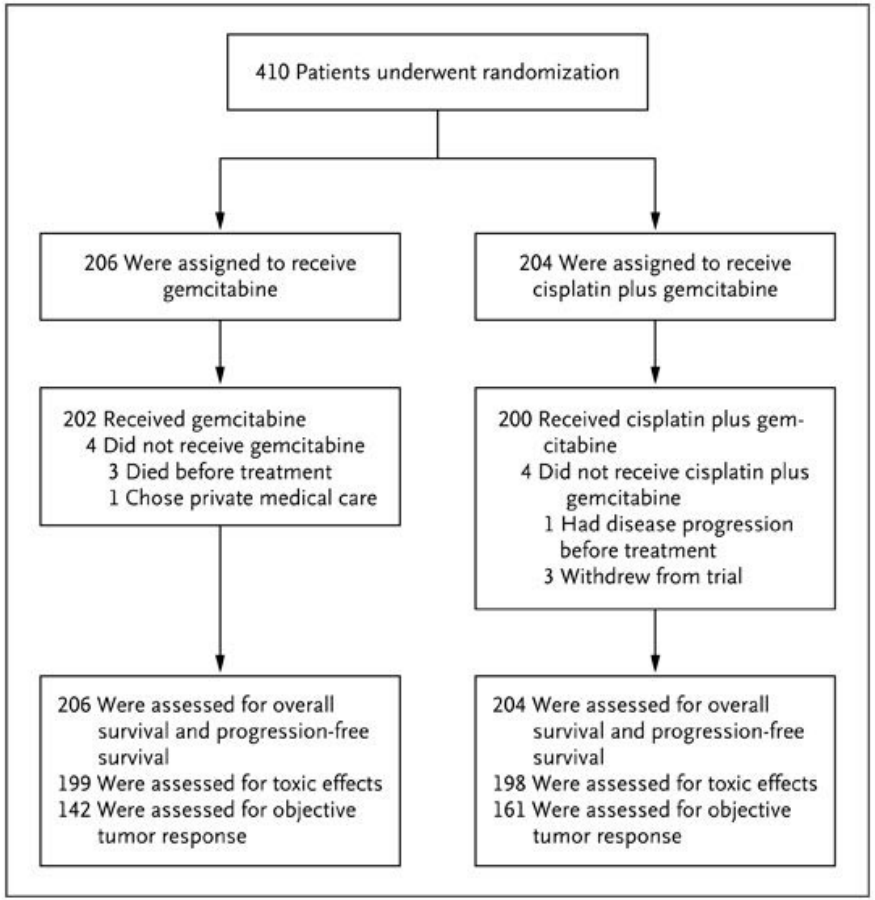
Cisplatin plus Gemcitabine versus Gemcitabine for Biliary Tract Cancer

Juan Valle, M.D., Harpreet Wasan, M.D., Daniel H. Palmer, M.D., Ph.D., David Cunningham, M.D., Alan Anthoney, M.D., Anthony Maraveyas, M.D., Ph.D., Srinivasan Madhusudan, M.D., Ph.D., Tim Iveson, M.D., Sharon Hughes, B.Sc., Stephen P. Pereira, M.D., Ph.D., Michael Roughton, M.Sc., John Bridgewater, M.D., Ph.D., for the ABC-02 Trial Investigators

N Engl J Med
Volume 362(14):1273-1281
April 8, 2010

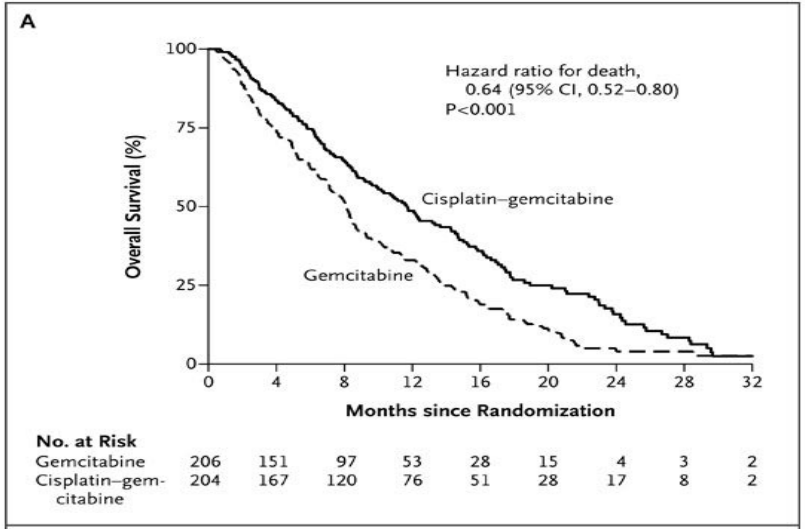
The NEW ENGLAND JOURNAL of MEDICINE

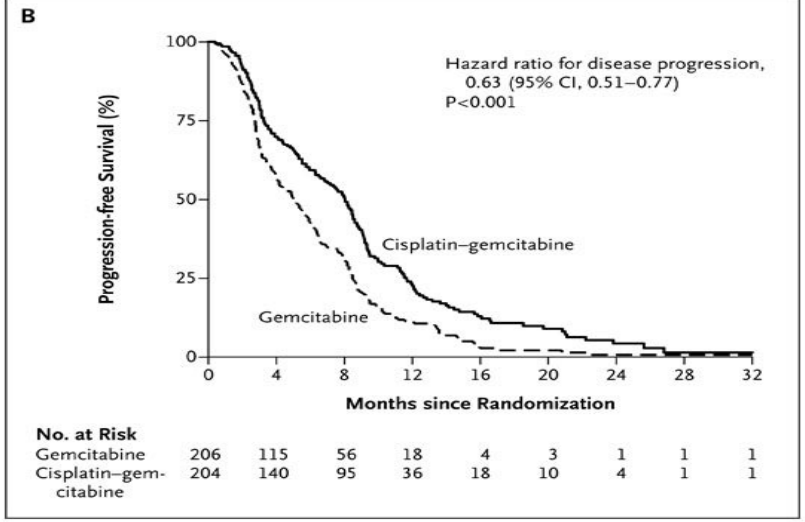
Patient Enrollment, Randomization, and Treatment



- The ABC-02 Study
- Published 2010
- Determined the current standard of care for first line treatment of advanced CCA

Valle J et al. N Engl J Med 2010;362:1273-1281





ABC-02 Outcomes

Median Overall Survival

Gem + Cis: 11.7 mos

Gem: 8.1 mos

Median Progression Free Survival

Gem + Cis: 8.0 mos

Gem: 5.0 mos

The NEW ENGLAND JOURNAL of MEDICINE

Valle J et al. N Engl J Med 2010;362:1273-1281

ASCO Gastrointestinal Cancers Symposium

A Phase 3 randomized, double-blind, placebo-controlled study of durvalumab in combination with gemcitabine plus cisplatin in patients with advanced biliary tract cancer: TOPAZ-1

Do-Youn Oh,[1] Aiwu Ruth He,[2] Shukui Qin,[3] Li-Tzong Chen,[4] Takuji Okusaka,[5] Arndt Vogel,[6] Jin Won Kim,[7] Thatthan Suksomboon charoen,[8] Myung Ah Lee,[9] Masayuki Kitano,[10] Howard Burris,[11] Mohamed Bouattour,[12] Suebpong Tanasanvimon,[13] Renata Zaucha,[14] Antonio Avallone,[15] Juan Cundom,[16] Nana Rokutanda,[17] Julia Xiong,[17] Gordon Cohen,[17] Juan W. Valle[18]

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TOPAZ-1 study design

TOPAZ-1 is a double-blind, multicenter, global, Phase 3 study

Key eligibility
- Locally advanced or metastatic BTC (ICC, ECC, GBC)
- Previously untreated if unresectable or metastatic at initial diagnosis
- Recurrent disease >6 months after curative surgery or adjuvant therapy
- ECOG PS 0 or 1

Stratification factors
- Disease status
  - (initially unresectable versus recurrent)
- Primary tumor location
  - (ICC versus ECC versus GBC)

R (1:1) N=685

Durvalumab 1500 mg Q3W + GemCis (up to 8 cycles) → **Durvalumab 1500 mg Q4W until PD**

Placebo Q3W + GemCis (up to 8 cycles) → **Placebo Q4W until PD**

Primary objective
- Overall survival

Secondary objectives
- Progression-free survival
- Objective response rate
- Duration of response
- Efficacy by PD-L1 status
- Safety

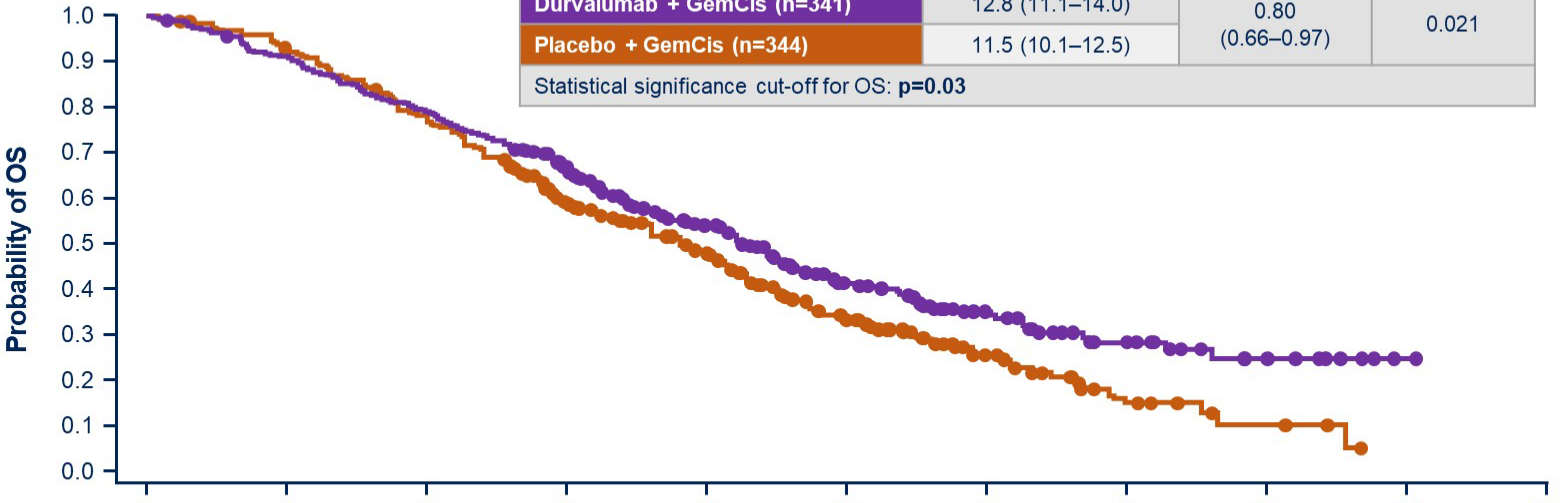
GemCis treatment: gemcitabine 1000 mg/m2 and cisplatin 25 mg/m2 on Days 1 and 8 Q3W administered for up to 8 cycles.

BTC, biliary tract cancer; ECC, extrahepatic cholangiocarcinoma; ECOG, Eastern Cooperative Oncology Group; GBC, gallbladder cancer; GemCis, gemcitabine and cisplatin; ICC; intrahepatic cholangiocarcinoma; PD, progressive disease; PD-L1, programmed cell death ligand-1; PS, performance status; QnW, every n weeks; R, randomization.

PRESENTED BY: Do-Youn Oh, MD, PhD

Primary endpoint: OS

	Median OS (95% CI), months	Hazard ratio (95% CI)	p-value
Durvalumab + GemCis (n=341)	12.8 (11.1–14.0)	0.80 (0.66–0.97)	0.021
Placebo + GemCis (n=344)	11.5 (10.1–12.5)		
Statistical significance cut-off for OS: **p=0.03**			

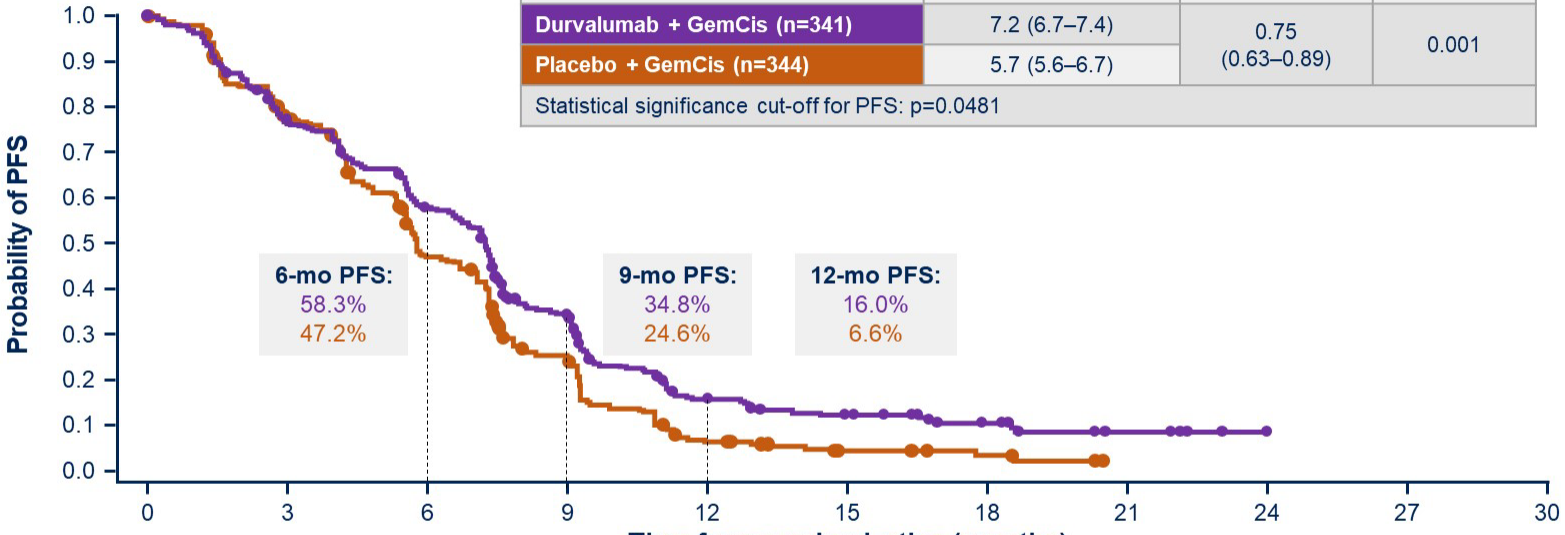


Number of subjects at risk										
Durvalumab + GemCis	341	309	268	208	135	79	49	24	9	1
Placebo + GemCis	344	317	261	183	125	65	29	10	4	0

Median duration of follow-up (95% CI) was 16.8 (14.8–17.7) months with durvalumab + GemCis and 15.9 (14.9–16.9) months with placebo + GemCis.
CI, confidence interval; GemCis, gemcitabine and cisplatin; HR, hazard ratio; mo, month; OS, overall survival.

Secondary endpoint: PFS

	Median PFS (95% CI), months	Hazard ratio (95% CI)	p-value
Durvalumab + GemCis (n=341)	7.2 (6.7–7.4)	0.75 (0.63–0.89)	0.001
Placebo + GemCis (n=344)	5.7 (5.6–6.7)		
Statistical significance cut-off for PFS: p=0.0481			

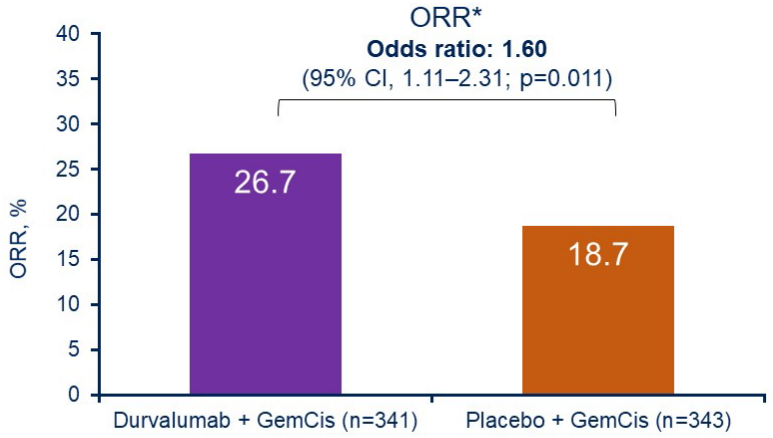


Number of subjects at risk

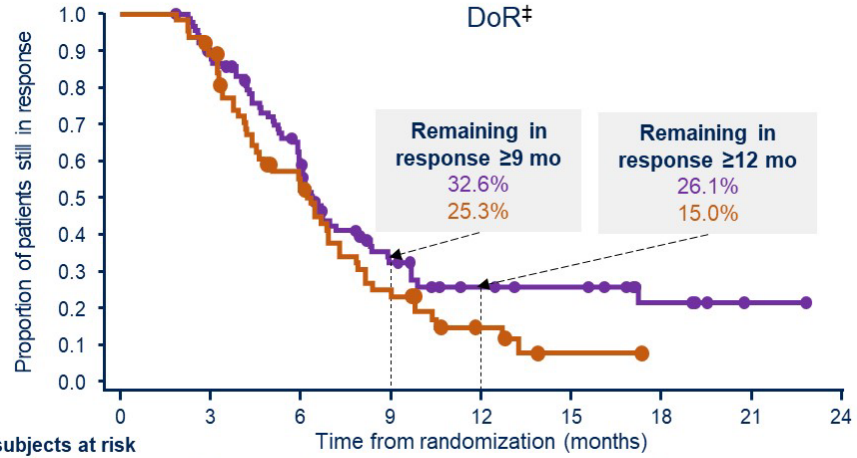
Durvalumab + GemCis	341	258	189	100	38	25	15	5	0
Placebo + GemCis	344	255	149	71	17	7	4	0	0

Median duration of follow-up (95% CI) was 9.2 (0.0–24.0) months with durvalumab + GemCis and 6.9 (0.0–20.4) months with placebo + GemCis.
CI, confidence interval; GemCis, gemcitabine and cisplatin; PFS, progression-free survival.

Secondary endpoint: Tumor response



	Durvalumab + GemCis (n=341)	Placebo + GemCis (n=343)
ORR, n (%)	91 (26.7)	64 (18.7)
CR, n (%)	7 (2.1)	2 (0.6)
PR, n (%)	84 (24.6)	62 (18.1)
DCR, n (%)†	291 (85.3)	284 (82.6)



Number of subjects at risk

Durvalumab + GemCis	91	79	49	22	13	11	5	1
Placebo + GemCis	64	56	31	14	5	1	0	0

	Durvalumab + GemCis (n=91)	Placebo + GemCis (n=64)
Median DoR (quartile 1–3), months	6.4 (4.6–17.2)	6.2 (3.8–9.0)
Median time to response (quartile 1–3), months	1.6 (1.3–3.0)	2.7 (1.4–4.1)

*By investigator assessments using RECIST v1.1 based on patients in the final analysis set who had measurable disease at baseline. †Analysis of DCR was based on all patients in the full analysis set. ‡Analysis of DoR was based on patients in the full analysis set who had an objective response and measurable disease at baseline.

CI, confidence interval; CR, complete response; DCR, disease control rate; DoR, duration of response; GemCis, gemcitabine and cisplatin; mo, month; ORR, objective response rate; PR, partial response.

PRESENTED BY: Do-Youn Oh, MD, PhD

Survival after 1st Line Therapy

- In ABC-02 and Topaz-1 median survival post progression was about 3 months

Unmet Need for Second Line Therapies for Cholangiocarcinoma

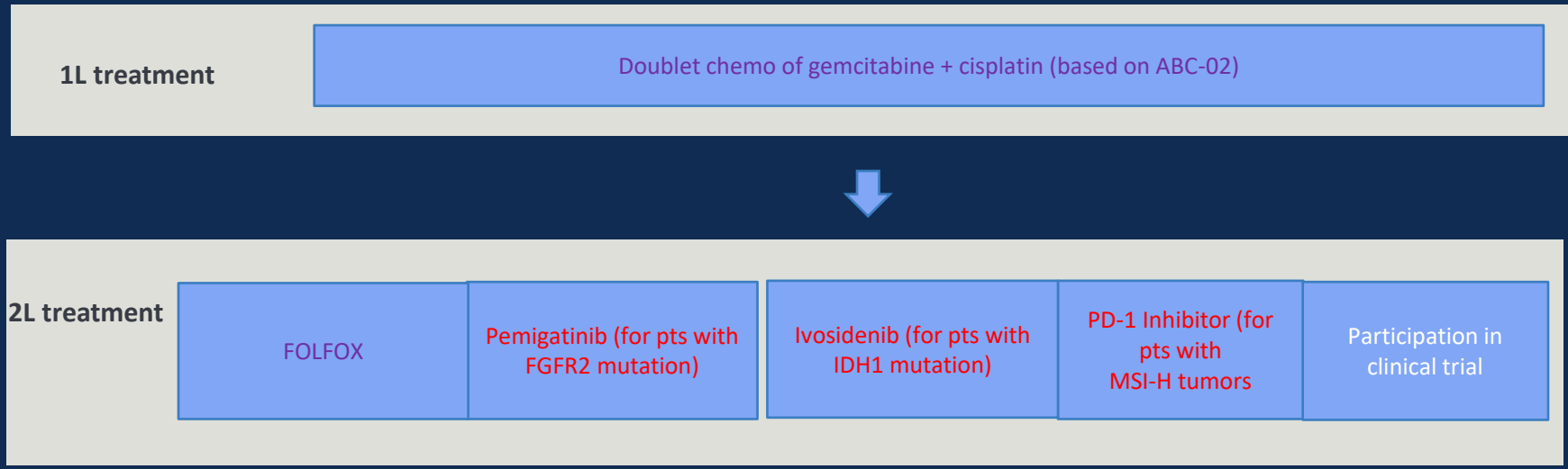
- Historical data of outcomes in 2L chemo-based therapies after gemcitabine/plat-based combo therapy failure result in dismal outcomes with limited progression free survival:

Author	Treatment	Phase	No. of patients	PFS (mo)	OS (mo)	ORR (%)
He *et al.*	FOLFOX-4	II	37	3.1	6.9	21.6
Paule *et al.*	Gem/oxa + cetuximab	II	9	4.0	7.0	11.0
Sasaki *et al.*	Irinotecan	II	13	1.8	6.7	7.7
Suzuki *et al.*	S-1	II	40	2.5	6.8	7.5
Fornaro *et al.*	Gem combination	Retrospective	174	3.0	6.6	3.4

Source: Ahn and Bekaii-Saab 2017*

*OS (mo) reported from He *et al.*, and ORR (%) reported from Paule *et al.* and Fornaro *et al.* are corrected.

Treatment Paradigm for BTC



Source: Adapted from NCCN guidelines

Targeted Therapy in BTC

- IDH-1 9.3%
- Microsatellite Instability (MSI-H) 4.3%
- NTRK fusion 0.75%
- FGFR fusion <0.50%

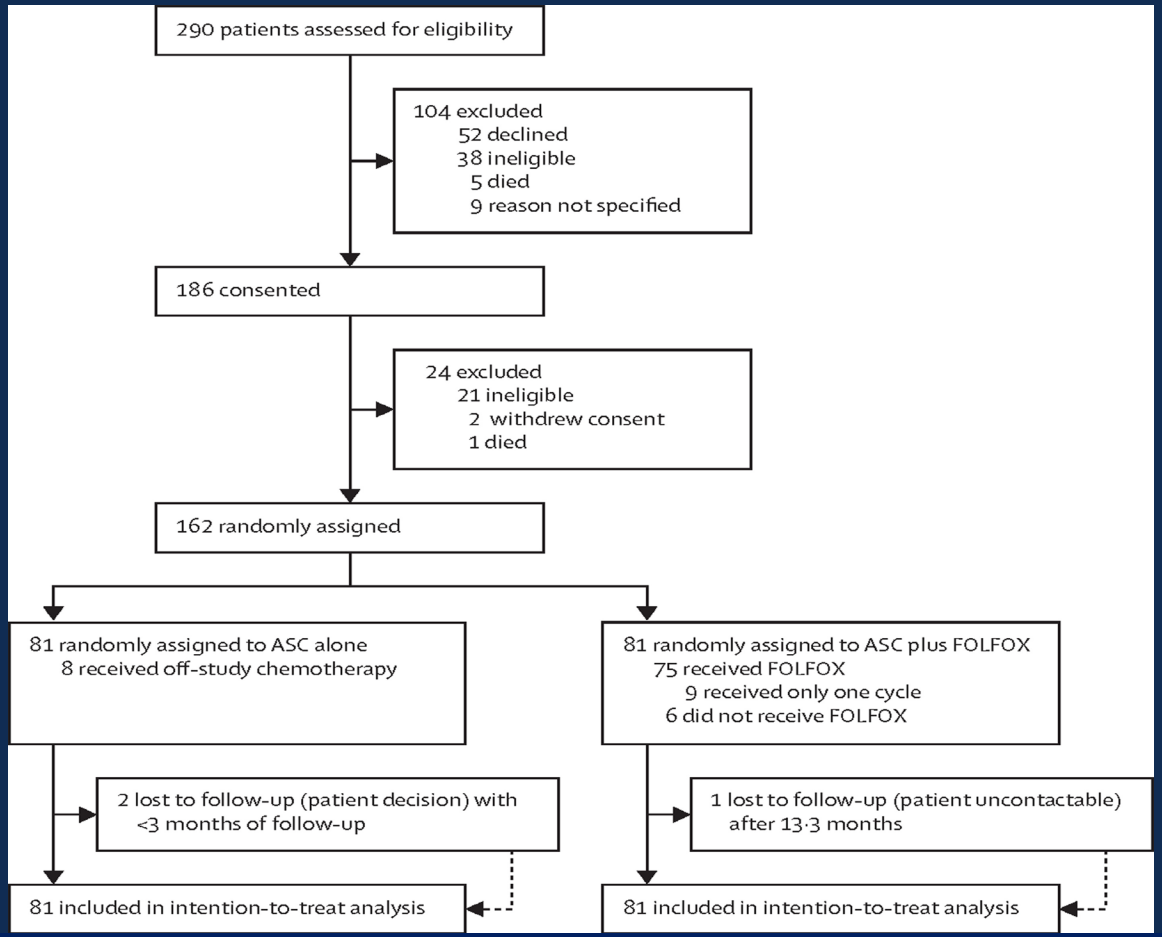
Eligible for current targeted therapies ~14%

Second-line FOLFOX chemotherapy versus active symptom control for advanced biliary tract cancer (ABC-06): a phase 3, open-label, randomised, controlled trial

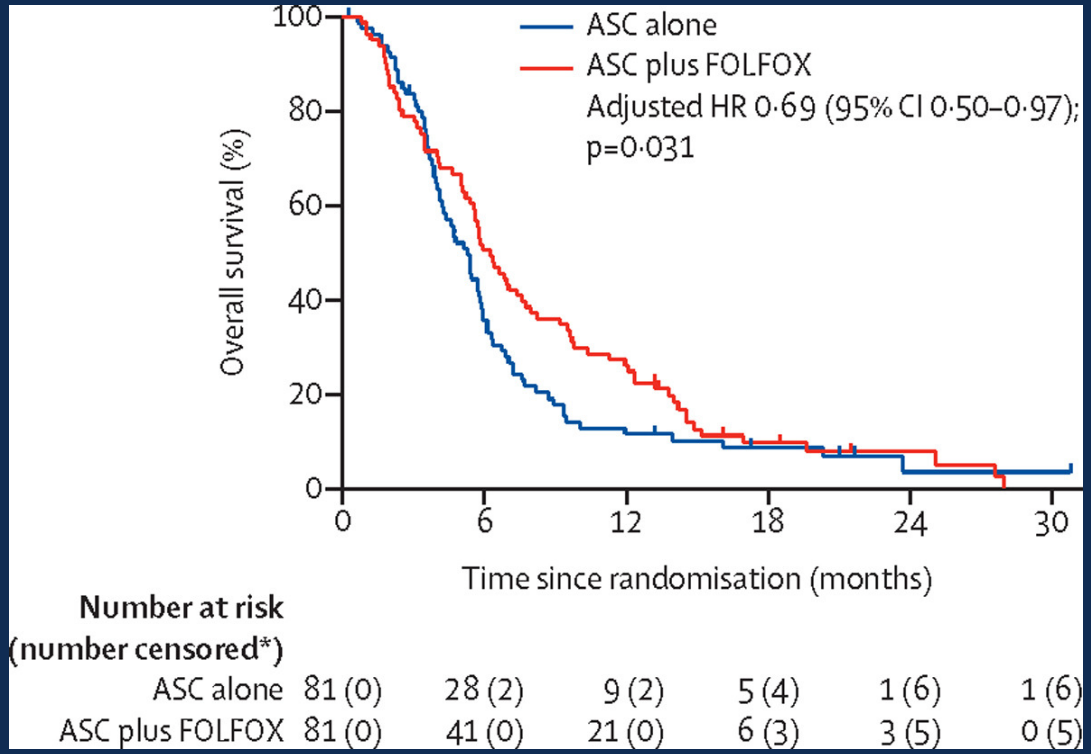
Angela Lamarca, PhD, Prof Daniel H Palmer, PhD, Harpreet Singh Wasan, MD, Paul J Ross, PhD, Yuk Ting Ma, PhD, Arvind Arora, MD, Stephen Falk, MD, Roopinder Gillmore, PhD, Prof Jonathan Wadsley, MA, Kinnari Patel, PhD, Alan Anthoney, MD, Prof Anthony Maraveyas, PhD, Prof Tim Iveson, MD, Justin S Waters, PhD, Claire Hobbs, MSc, Safia Barber, BSc, W David Ryder, Grad.IS, Prof John Ramage, MD, Prof Linda M Davies, MSc, Prof John A Bridgewater, PhD, Prof Juan W Valle, MD

The Lancet Oncology
Volume 22 Issue 5 Pages 690-701 (May 2021)
DOI: 10.1016/S1470-2045(21)00027-9

ABC-06 Trial Schema



Median Survival



Number at risk (number censored*)						
ASC alone	81 (0)	28 (2)	9 (2)	5 (4)	1 (6)	1 (6)
ASC plus FOLFOX	81 (0)	41 (0)	21 (0)	6 (3)	3 (5)	0 (5)

<u>Median Overall Survival</u>
ASC + FOLFOX: 6.2 mos
ASC: 5.3 mos

Patient selection explains
The longer OS

Chemotherapy in BTC

- NCCN Guidelines
  - First Line: Gem/Cis doublet
    - 26.1% ORR
    - 3.6 month increase in median OS vs. Gem alone (HR=0.64)
    - Valle, et al. (2010)
  - Second-line: FOLFOX
    - 5% ORR
    - 0.9 month increase in median OS vs. supportive care (HR=0.69)
    - Lamarca, et al. (2021)
- Taxanes
  - Neither paclitaxel nor docetaxel are recommended by NCCN
  - Paclitaxel: No responses in a 15 patient first-line study [Jones, et al. (1996)]
  - Docetaxel: No responses in a 17 patient first-and second-line study [Pazdur, et al. (1999)]
  - Nab-Paclitaxel is under investigation, but preferred first line regimen is Gem/Cis per NCCN Guidelines

There clearly are unmet needs in managing BTC

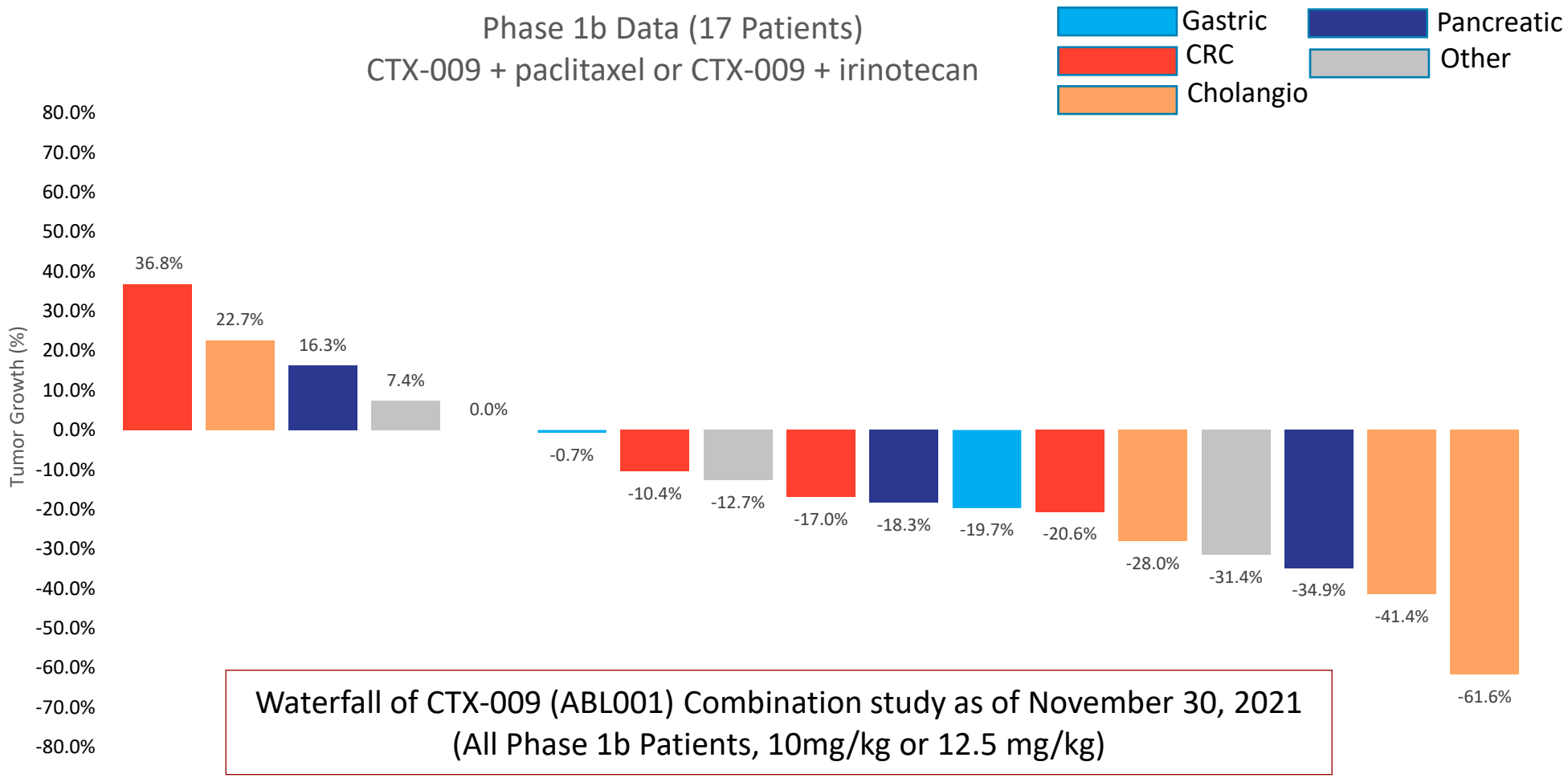
CTX-009 Update: Executive Summary

- **Phase 1:** 8 PRs in patients with advanced cancers both as a monotherapy and in combination with chemotherapy with an acceptable safety profile
- **Phase 2 (Stage 1):** CTX-009 in combination with paclitaxel in patients with BTC is ongoing
  - Interim update (data as of April 14, 2022)
  - 24 patients with BTC have been enrolled and dosed
  - As of 4/14; **10 PRs** for a **42% ORR** (10/24)
  - Responses observed across all 4 BTC subtypes
  - Median time on study is ~6 months
  - Adverse event profile similar to Phase 1 studies
- **Phase 2 (Stage 2):** Plan to initiate Stage 2 in the US in early Q3

Phase 1b Combination Study with Chemo (N=17)

- 4 arms:
  - 10.0 and 12.5 mg/kg CTX-009
  - Irinotecan or paclitaxel
- Activity:
  - 4 PRs, 3 confirmed, including a confirmed PR in pancreatic cancer
  - 9 Stable Disease (SD)
- Overall Response Rate (ORR): 24%
- Clinical Benefit Rate (CBR): 77% (PR + SD)

Phase 1b Combination Study Waterfall Plot



Waterfall of CTX-009 (ABL001) Combination study as of November 30, 2021
(All Phase 1b Patients, 10mg/kg or 12.5 mg/kg)

Phase 1b Combination Safety Data

Drug-related adverse events observed in > 1 patient	Total (n)	Total (%)	Grade 3 (n)	Grade 3 (%)
Hypertension*	5	29%	4	24%
Pulmonary hypertension (all grade 1)	5	29%	0	0%
Neutropenia** Anemia** Thrombocytopenia**	4 3 2	24% 18% 12%	3 3 2	18% 18% 12%
Proteinuria	3	18%	0	0%
Dyspnea	3	18%	0	0%
Fatigue	3	18%	0	0%
Anorexia	3	18%	0	0%
Gingival edema (mucositis)	2	12%	0	0%
Nausea	2	12%	1	6%
Anal hemorrhage	2	12%	0	0%

*In clinical trials of bevacizumab, incidence of Grade 3-4 hypertension ranged between 5%-18% (Avastin label). It is typically managed by anti-hypertensive drugs.
**Labeled Grade 3/4 cytopenia events for concomitant chemotherapy agent:
Irinotecan: 31.4% neutropenia, 4.5% anemia, 1.7% thrombocytopenia
Paclitaxel: 52% neutropenia, 16% anemia, 7% thrombocytopenia

Phase 2 Combination Study: CTX-009 Plus Paclitaxel

Phase 2 Study Design:

- Patients with biliary tract cancers after one or two prior therapies
- CTX-009 at 10 mg/kg biweekly plus paclitaxel 80 mg/m^2 weekly 3 of 4 weeks
- Simon 2 Stage adaptive design:
  - Stage 1: 21 patients → ORR
  - Stage 2: if 3 or more PRs → Stage 2: 45 additional patients

Phase 2 Combination Study Status

- November 1, 2021 (previously reported interim data)
  - 24 patients had been enrolled; 17 patients evaluable for response
  - Efficacy data: **5 PRs; 29% ORR**

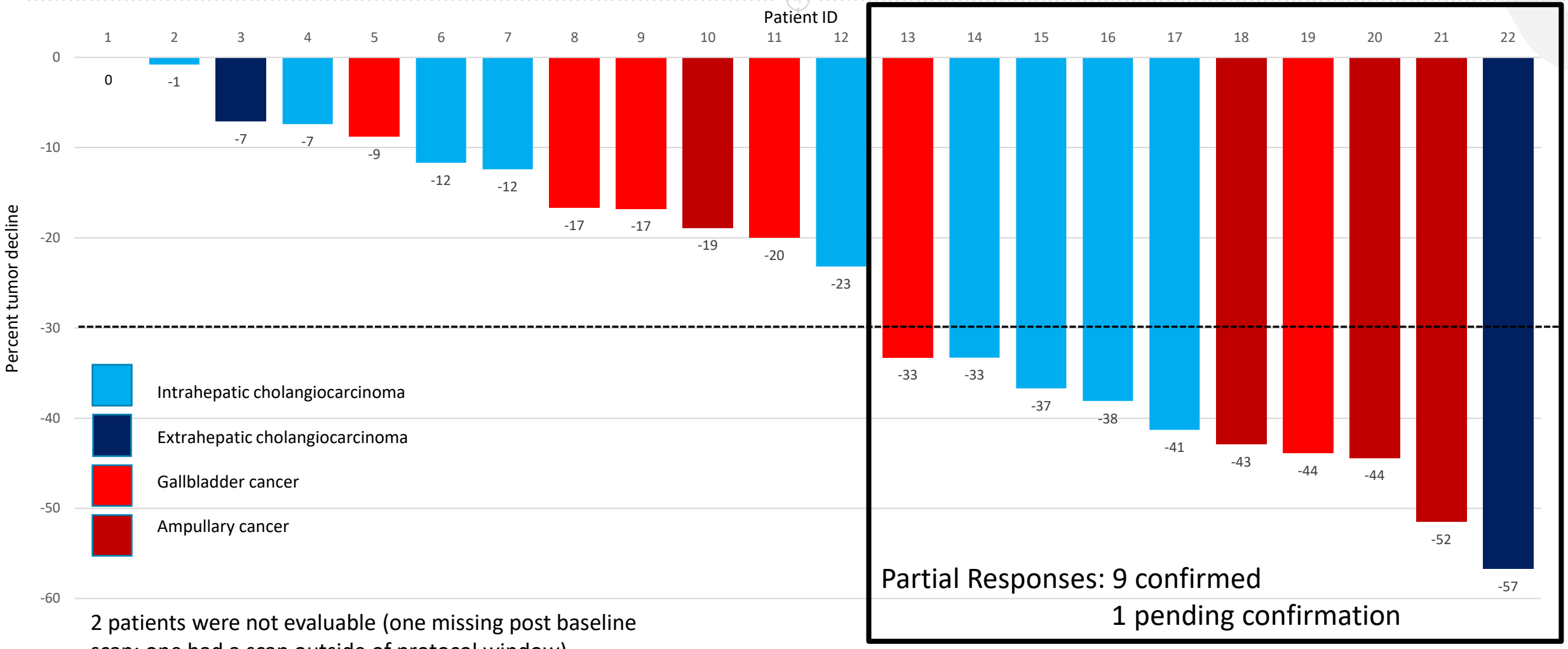
- April 14, 2022 (interim data)
  - 24 patients enrolled; 22 patients evaluable for response
  - Efficacy data: **10 PRs; 42% ORR**
  - Plan to proceed to Stage 2 in the US and Korea

Phase 2: Patient Baseline and Demographics

	24 Total Patients
Age	
Median (years)	61.5
Gender, n(%)	
Male	14 (58%)
Female	10 (42%)
ECOG performance status, n(%)	
0	13 (54%)
1	11 (46%)

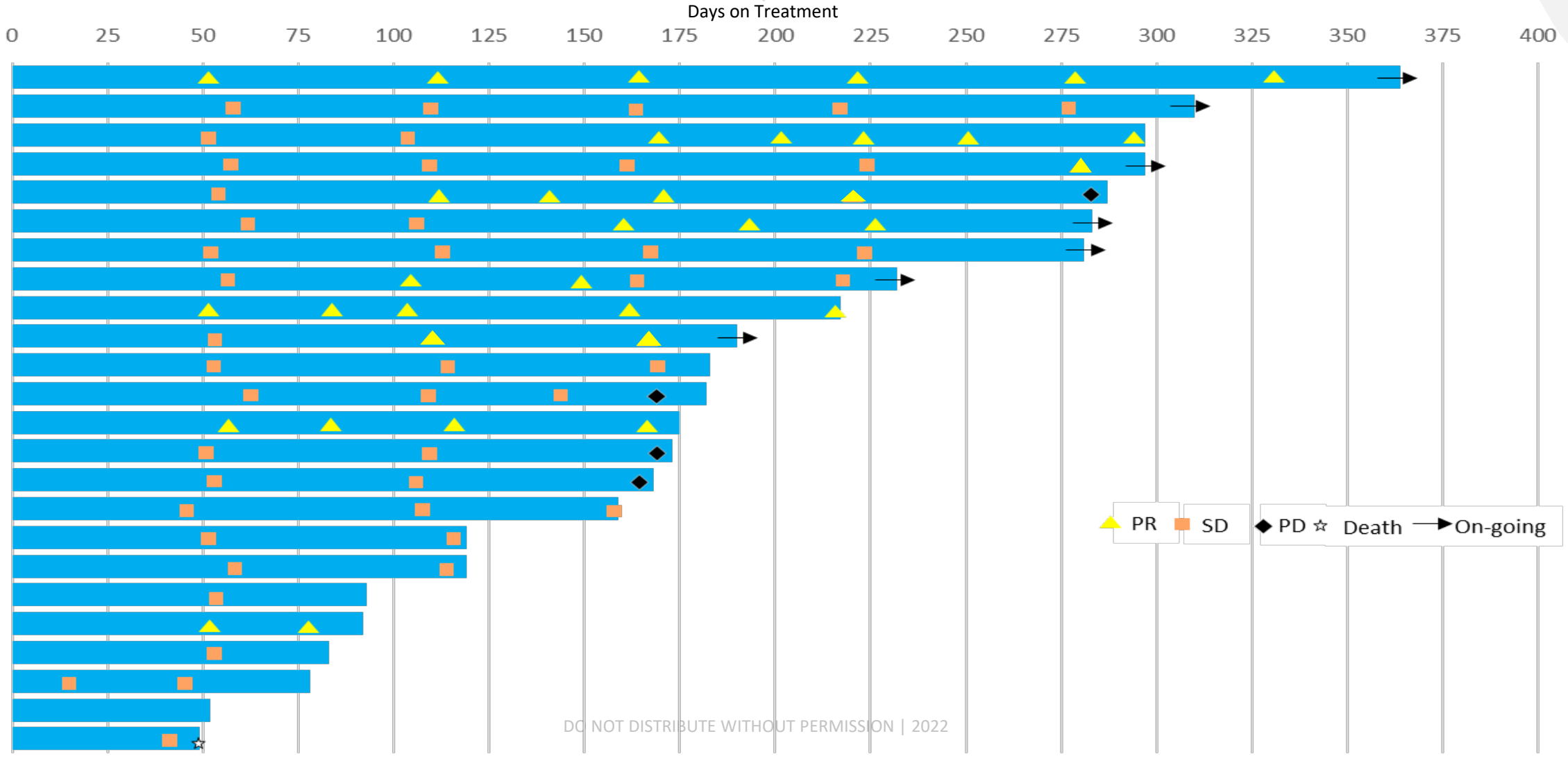
	24 Total Patients
Prior systemic therapies, n(%)	
1	11 (46%)
2	13 (54%)
Prior Gem/Cis regimen	23 (96%)
BTC subtype, n (%)	
Intrahepatic cholangiocarcinoma	9 (38%)
Extrahepatic cholangiocarcinoma	3 (13%)
Gallbladder cancer	7 (29%)
Ampullary cancer	5 (21%)

Phase 2 Waterfall: ORR = 42%; CBR = 92%



2 patients were not evaluable (one missing post baseline scan; one had a scan outside of protocol window)

Swimmer Plot: Median Time on Study ~ 6 Months



Safety Data: Treatment-Related ≥ Grade 3 Adverse Events

Phase 2 BTC study of CTX-009 plus paclitaxel

Event	24 total Patients N (%)
Neutropenia	12 (50.0%)
Hypertension	4 (16.7%)
Anemia	3 (12.5%)
Thrombocytopenia	2 (8.3%)
Additional events observed in 1 patient: Intestinal perforation, Asthenia, Catheter site hemorrhage, Fatigue, Cholangitis, Abdominal infection, Bacterial gastritis, Pneumonia (fatal), Post-procedure hemorrhage, Decreased appetite, Cerebral hemorrhage, Proteinuria, Embolism	

Avastin and paclitaxel label information

Event	Avastin (label)	Paclitaxel (label)
Neutropenia		52%
Hypertension	5-18%	
Anemia		16%
Thrombocytopenia		7%
	Additional events: GI perforation, wound healing complications, Proteinuria, hemorrhage	Additional events: Hypersensitivity reactions, infections, bleeding, neuropathy

CTX-009 Next Steps

- Initiate Stage 2 of the Phase 2 BTC study in the US in early Q3
- Initiate Phase 2/3 study in patients with colorectal cancer in the third line setting in the US in Q4 2022
- Initiate Phase 2 study in patients with advanced ovarian cancer in the US in Q1 2023
- Continue to evaluate additional indications for CTX-009 both as a monotherapy and in combination with chemotherapy

CTX-009 Interim Phase 2 Study Summary

- 24 patients with BTC have been enrolled and dosed
- 10 partial responses (PRs) for a **42% ORR** in patients treated in the second- and third-line settings (54% of patient were treated in the 3rd line setting)
- Other regimens in BTC:
  - FOLFOX (NCCN guidelines): 5% ORR in the second-line setting
  - TOPAZ-1 (Phase 3 development): 26.7% ORR for Gem/Cis/Durvalumab (anti-PD-L1) in the first-line setting
- Median time on study approximately 6 months, with 7 patients ongoing
- Adverse event profile similar to Phase 1