

# XX JORNADA DE ACTUALIZACIÓN ASCO GI 2026

24 de febrero de 2026

## ¿Qué hay de nuevo en los tumores hepato-bilio-pancreáticos?

**Dra. Teresa Macarulla**

Hospital Clínic, Barcelona



## DISCLOSURES

### **Consultant or Advisory Role**

- Amgen, Servier, Incyte, Sanofi, AstraZeneca, Taiho, Celgene, Eisai

### **Institutional financial interests (financial support to research projects):**

- Celgene, AstraZeneca, BeiGene, Incyte

### **Non-financial interests:**

- AstraZeneca, Incyte, Servier, Roche, Eisai, MSD



## **Tumores pancreáticos**

### **Oral presentation**

Preliminary phase 1 results of INCB161734, a novel oral KRAS G12D inhibitor, as monotherapy or in combination with chemotherapy for advanced/metastatic PDAC.

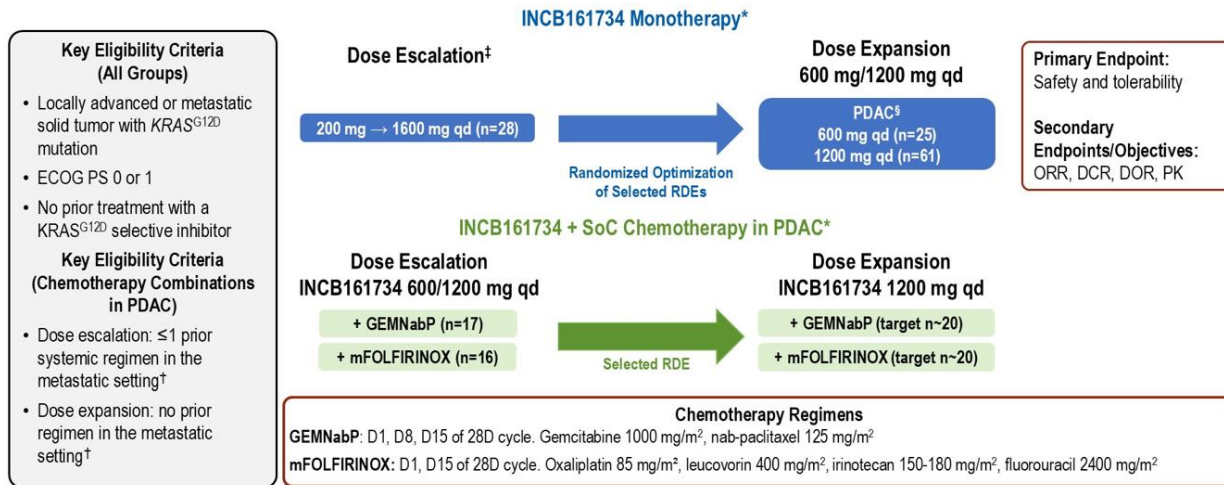
### **Rapid oral abstract presentation**

- Results from the randomized phase 2 study of elraglusib plus gem/nab versus gem/nab in previously treated mPDAC.
- Integrated penpulimab (a PD-1 inhib), anlotinib (antiangiogenic), nab and gemas 1L regiment for mPDAC. Multi-centered, randomized controlled trial
- Phase II study of durvalumab plus olaparib in patients with mPDAC and DNA damage repair alterations
- ALTOPANC: Local ablative therapies in oligometastatic PDAC-A binational french-Belgian retrospective study.



# Preliminary phase 1 results of INCB161734, a novel oral KRAS G12D inhibitor, as monotherapy or in combination with chemotherapy for advanced/metastatic PDAC.

## INCB161734-101 (NCT06179160): Study Design



INCB161734 is a novel, selective ON/OFF oral KRAS G12D inhibitor

\*As of November 11, 2025. †Neoadjuvant or adjuvant therapy may be counted as 1 line of therapy if recurrence/development of metastatic disease occurred within 6 months of last dose of therapy; patients who received no standard systemic therapy for PDAC may have received ≤1 cycle of GEMNabP or mFOLFIRINOX before enrolling, with last dose ≥7 days before cycle 1, day 1. ‡Included doses of 200-1600 mg qd and 600 mg bid. Additional cohorts of patients included the pharmacodynamic evaluation cohort (n=9) and the food-effect cohort (n=17). §Included patients in the pharmacodynamic evaluation and food-effect cohorts. ||bid, twice daily; CRC, colorectal cancer; D, day; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; GEMNabP, nab-paclitaxel + gemcitabine; mFOLFIRINOX, modified leucovorin calcium, fluorouracil, irinotecan hydrochloride, oxaliplatin; ORR, objective response rate; PDAC, pancreatic ductal adenocarcinoma; PK, pharmacokinetics; qd, daily; RDE, recommended dose for expansion; SoC, standard of care.

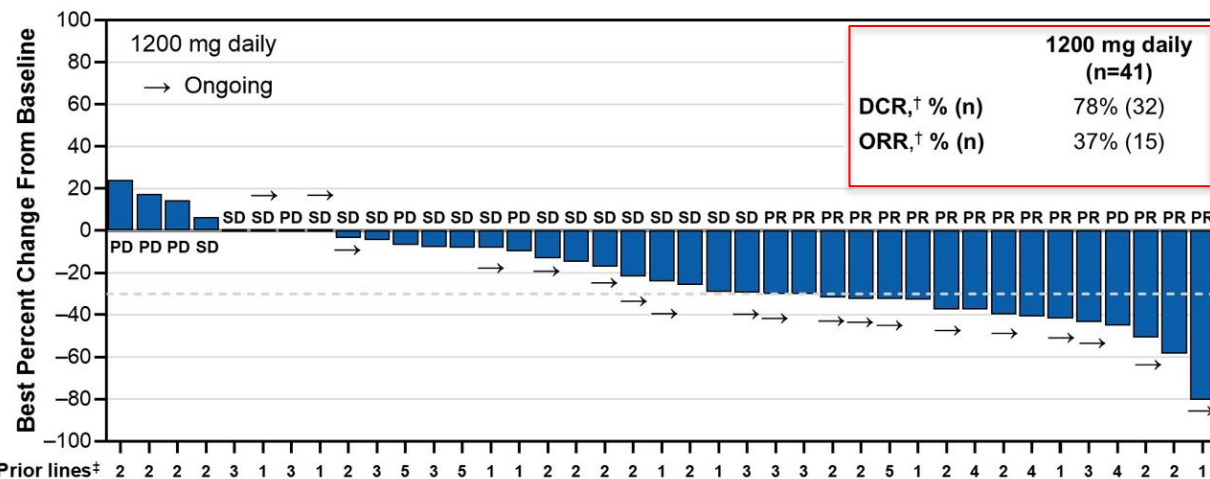


# Preliminary phase 1 results of INCB161734, a novel oral KRAS G12D inhibitor, as monotherapy or in combination with chemotherapy for advanced/metastatic PDAC.

## INCB161734 Monotherapy Showed Encouraging Antitumor Activity in Heavily Pretreated Patients With PDAC

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- High ORR and DCR for patients with PDAC (mainly 3L+) who received INCB161734 1200 mg daily\*



\*INCB161734 600 mg bid or 1200 mg qd. †Investigator-assessed per RECIST v1.1 in patients with a baseline scan who either completed ≥2 postbaseline scans or discontinued due to clinical progression or death. Missing data: death before first scan (n=1) and no target lesion measurement recorded (n=1). ‡In the advanced/metastatic setting. 3L, third-line; bid, twice daily; DCR, disease control rate; ORR, objective response rate; PD, progressive disease; PDAC, pancreatic ductal adenocarcinoma; qd, daily; RECIST, Response Evaluation Criteria in Solid Tumors; SD, stable disease.

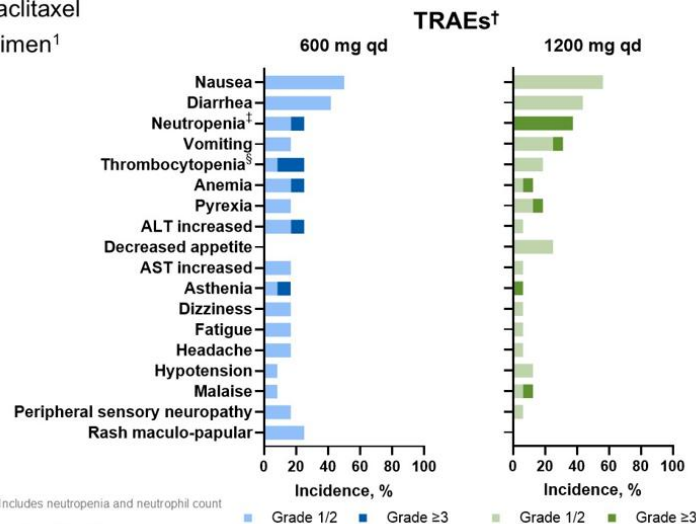


# Preliminary phase 1 results of INCB161734, a novel oral KRAS G12D inhibitor, as monotherapy or in combination with chemotherapy for advanced/metastatic PDAC.

## INCB161734 in Combination With GEMNabP Was Well Tolerated Without Compromising Chemotherapy Dose Intensity

- 46% of patients were 2L and had received prior systemic chemotherapy
- Median RDI was 74% for both gemcitabine and nab-paclitaxel
  - Comparable to previous reports for GEMNabP regimen<sup>1</sup>

TRAE,* n (%)	GEMNabP	
	600 mg qd (n=12)	1200 mg qd (n=16)
	All Grades	All Grades
Any TRAE	12 (100)	14 (87.5)
TRAE leading to INCB161734		
Interruption	7 (58.3)	7 (43.8)
Reduction	0 (0)	1 (6.3)
Discontinuation	0 (0)	0 (0)
TRAE leading to chemotherapy		
Interruption	8 (66.7)	6 (37.5)
Reduction	3 (25.0)	7 (43.8)
Discontinuation	1 (8.3)	0 (0)



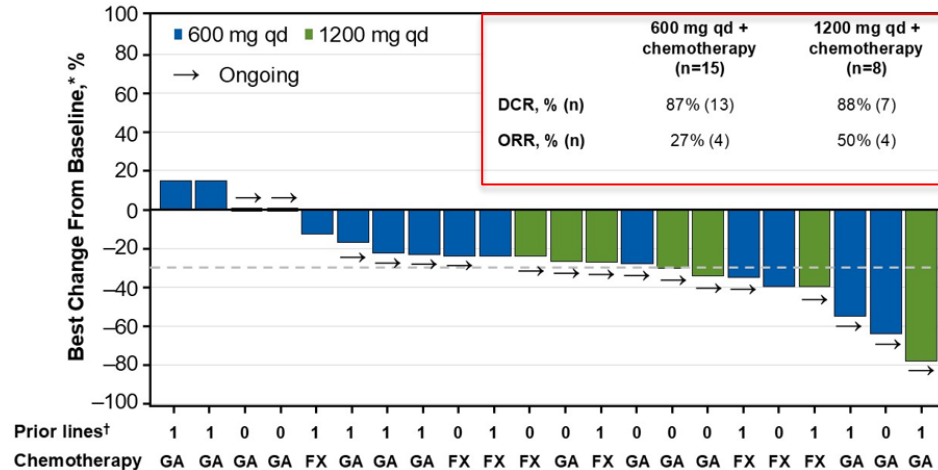
1. Von Hoff DD, et al. *N Engl J Med*. 2013;369(18):1691-1703.  
 \*Assessed in patients who received ≥1 dose of study drug. †Including only TRAEs that occurred in ≥10% of patients. ‡Includes neutropenia and neutrophil count decreased. §Includes thrombocytopenia and platelet count decreased.  
 2L, second-line; ALT, alanine aminotransferase; AST, aspartate aminotransferase; GEMNabP, nab-paclitaxel + gemcitabine; qd, daily; RDI, relative dose intensity; TRAE, treatment-related adverse event.



# Preliminary phase 1 results of INCB161734, a novel oral KRAS G12D inhibitor, as monotherapy or in combination with chemotherapy for advanced/metastatic PDAC.

## INCB161734 With SoC Chemotherapy Showed Encouraging Antitumor Activity in Patients With 1L or 2L Metastatic PDAC

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\*Investigator-assessed per RECIST v1.1 in patients with ≥1 postbaseline scan or who discontinued due to clinical progression or death. Missing data: death before first scan (n=1). †In the advanced/metastatic setting. 1L, first-line; 2L, second-line; DCR, disease control rate; FX, modified leucovorin calcium, fluorouracil, irinotecan hydrochloride, oxaliplatin; GA, nab-paclitaxel + gemcitabine; ORR, objective response rate; PDAC, pancreatic ductal adenocarcinoma; qd, daily; RECIST, Response Evaluation Criteria in Solid Tumors; SoC, standard of care.



# Where we are going in the future with RAS inhibitors: The sky is the limit?

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Chemotherapy-refractory advanced/metastatic disease

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Front-line advanced/metastatic disease in combination with chemorx ...or as monotherapy?

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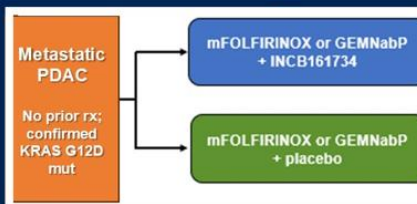
Adjuvant (or neoadjuvant) setting – in combo with, after, or in lieu of chemorx

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'Maintenance' treatment (all disease settings)

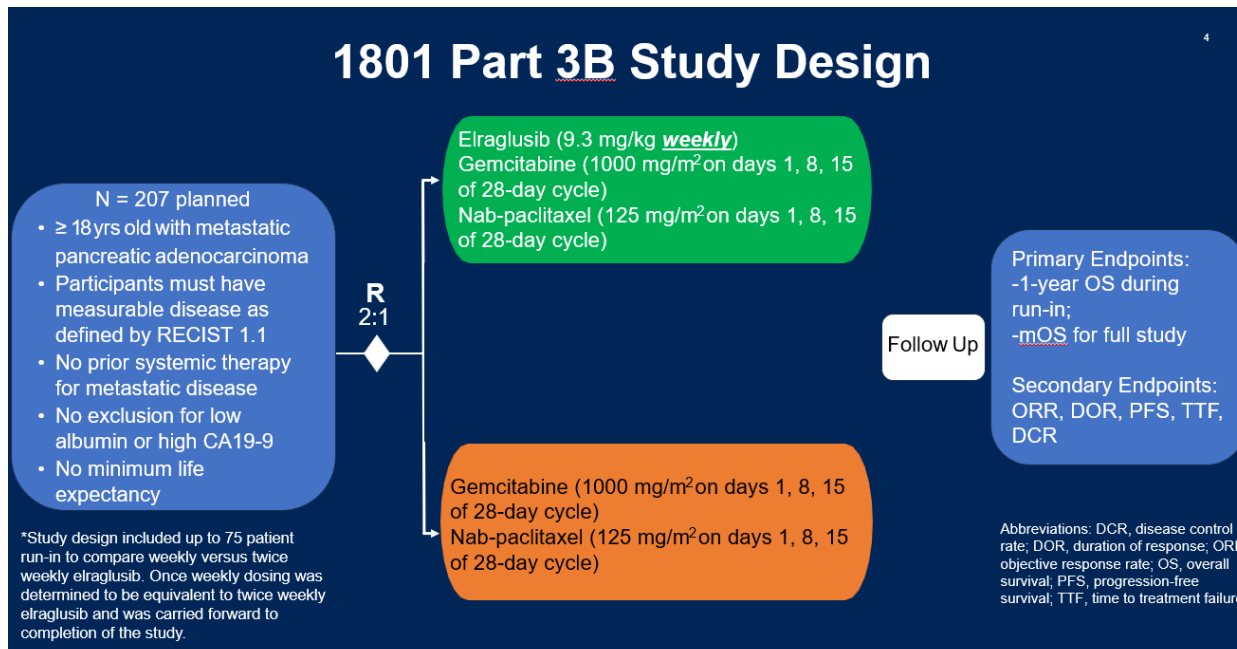
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Novel combinations (e.g. with other targeted rxs or IO)





# Results from the randomized phase 2 study of elraglusib plus gem/nab versus gem/nab in previously treated mPDAC.





# Results from the randomized phase 2 study of elraglusib plus gem/nab versus gem/nab in previously treated mPDAC.

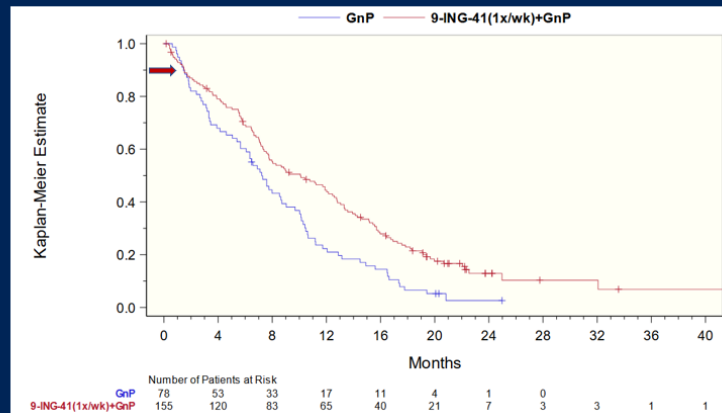
## Met Primary Efficacy Endpoint of Improved Survival

38% reduction in risk of death in safety population/MITT

17% of patients still alive in elraglusib/GnP arm as of 22 November 2025 data cutoff

	Elraglusib/GnP (N = 155)	GnP (N = 78)
Primary Endpoint: mOS (months)[95%CI]	10.1 [7.7, 12.6]	7.2 [5.7, 9.0]
HR=0.62; log-rank p=0.02*		
12-month OS (%)	44.4	22.3
Events (% event)	128 (82.6)	74 (94.9)
18-month OS (%)	22.9	6.6
24-month OS (%)	12.9	2.6

\*statistically significant  
Abbreviations: GnP, gemcitabine plus nab-paclitaxel; HR, hazard ratio;  
mOS, median overall survival; OS, overall survival

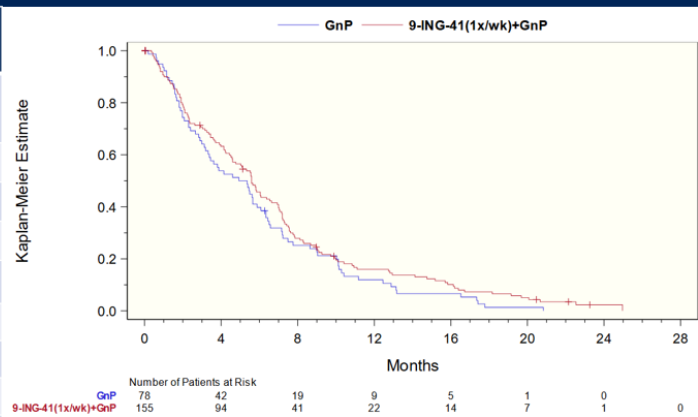




# Results from the randomized phase 2 study of elraglusib plus gem/nab versus gem/nab in previously treated mPDAC.

## Progression-Free Survival (PFS) and ORR-mITT

Safety Population	Elraglusib/GnP (N = 155)	GnP (N = 78)
<b>mPFS (months)</b> HR=0.83; log-rank p=NS	5.6	5.1
Events (% events)	143 (92.3)	77 (98.7)
<b>TTF (months)</b> HR=0.78; p=NS	5.0	3.4
<b>ORR, %</b>	28.4	21.8
<b>Best response, n (%)</b>		
Complete Response	1 (0.6)	0
Partial Response	43 (27.8)	17 (21.8)
Stable Disease	51 (32.9)	27 (34.6)
Progressive Disease	21 (13.5)	15 (19.2)
Not Evaluable/Unknown	39 (25.2)	19 (24.4)
<b>DCR<sup>b</sup>, %</b>	40.6	33.3
<b>Median DOR (months)<sup>a</sup></b>	5.5	4.1

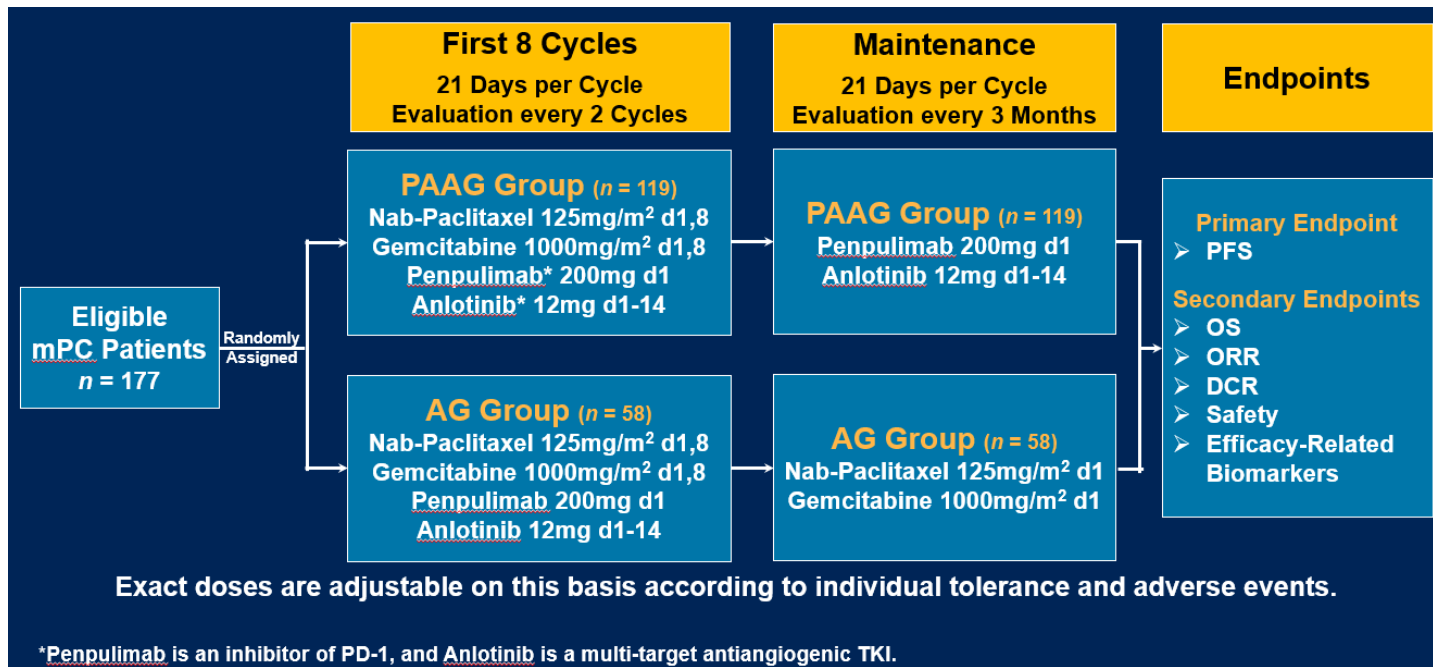


Abbreviations: GnP, gemcitabine plus nab-paclitaxel; HR, hazard ratio; mPFS, median progression-free survival; NS, not significant; TTF, time to treatment failure

Data cutoff 22 November 2025



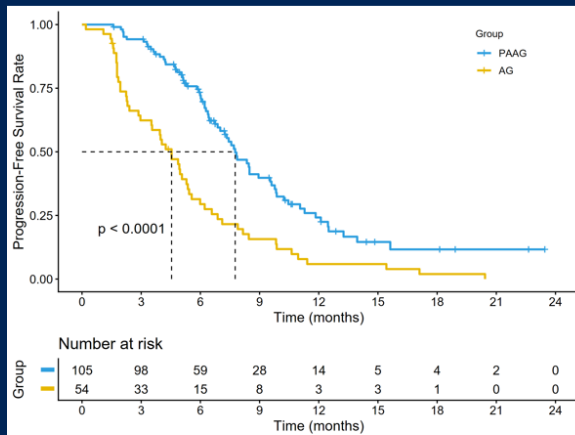
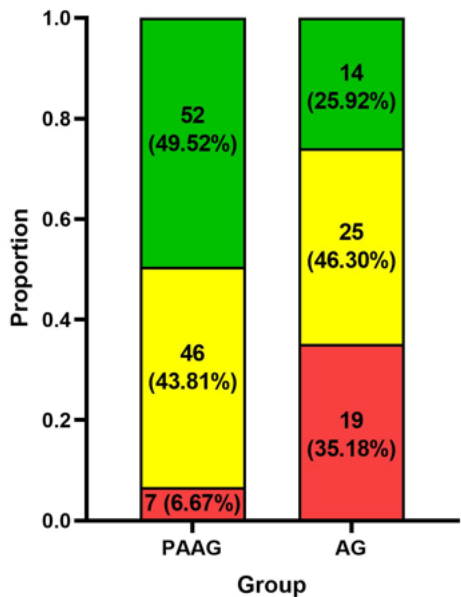
Integrated penpulimab (a PD-1 inhib), anlotinib (antiangiogenic), nab and gemas 1L regiment for mPDAC. Multi-centered, randomized controlled trial



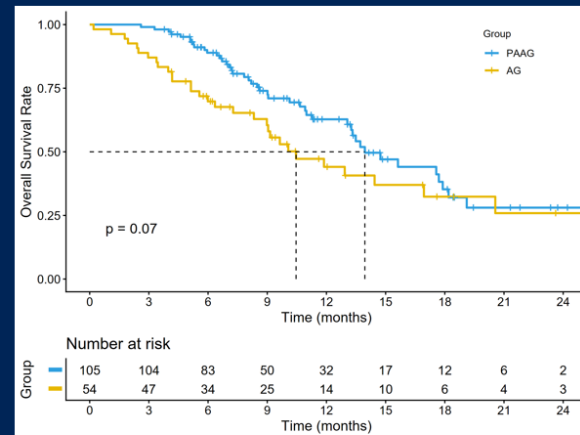


# Integrated penpulimab (a PD-1 inhib), anlotinib (antiangiogenic), nab and gemas 1L regimen for mPDAC. Multi-centered, randomized controlled trial

BOR ■ CR&PR ■ SD ■ PD



Group	mPFS	95%CI	P-Value
PAAG	7.8 mo	7.0 ~ 8.8 mo	<b>&lt; 0.001**</b>
AG	4.5 mo	3.6 ~ 5.5 mo	



Group	mOS	95%CI	P-Value
PAAG	13.9 mo	11.6 ~ 16.3 mo	0.070
AG	10.5 mo	6.9 ~ 14.0 mo	



# Phase II study of durvalumab plus olaparib in patients with metastatic pancreatic cancer and DNA damage repair genes alterations

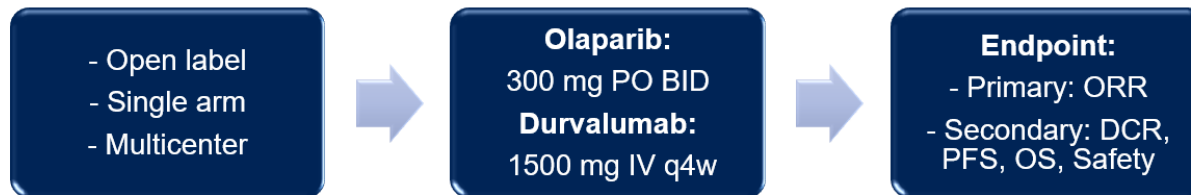
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## Background and study design

Metastatic pancreatic cancer (mPC) with DNA damage repair (DDR) alterations such as *BRCA1*, *BRCA2* and *PALB2* is associated with sensitivity to platinum-based chemotherapy (CT) and PARP inhibition.

Evidence suggests PARP inhibition with immune checkpoint blockade may enhance antitumor activity.

This study evaluates the combination of durvalumab and olaparib in DDR-mutated mPC patients with no progression to platinum-based CT.



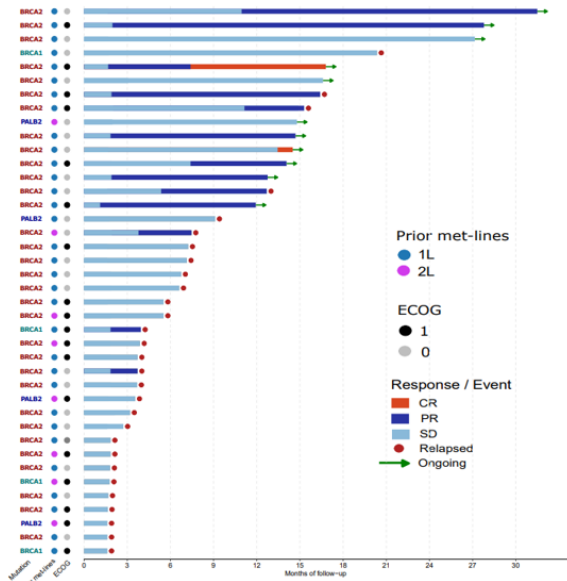


# Phase II study of durvalumab plus olaparib in patients with metastatic pancreatic cancer and DNA damage repair genes alterations

## Results (ORR, DCR, DoR)

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Swimmer plot



Objective response rate (ORR) and disease control rate (DCR)

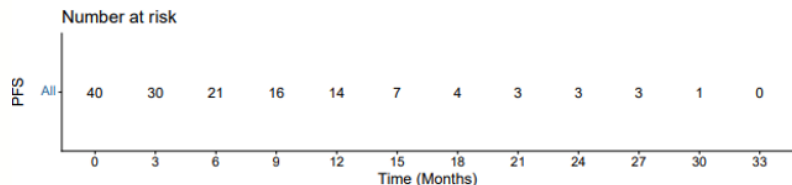
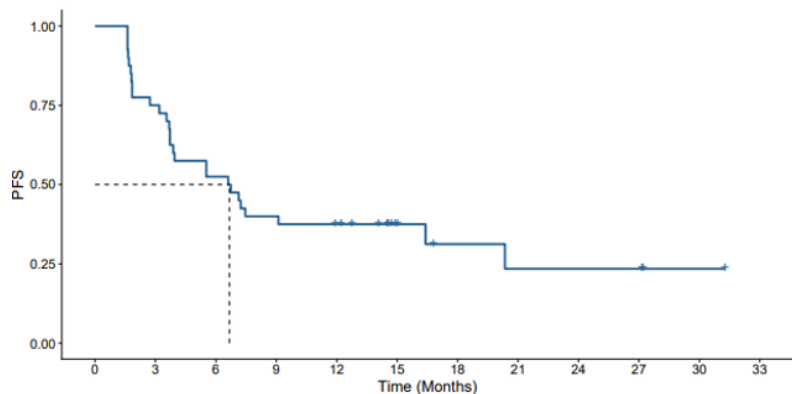
Characteristic	N = 40 (%)
Median follow up months (95% CI)	15.0 (14.5, 24.9)
<b>Objective response</b>	
Complete Response (CR)	2 (5.0%)
Partial Response (PR)	12 (30.0%)
Stable Disease (SD)	17 (42.5%)
Progressive Disease (PD)	9 (22.5%)
<b>ORR (CR + PR)</b>	14 (35.0%)
<b>DCR (CR + PR + SD)</b>	31 (77.5%)
<b>DCR 6 months</b>	23 (57.5%)
<b>Median DoR months (95% CI)</b>	14.5 (14.5, -)
<b>Ongoing response</b>	13 (32.5%)



# Phase II study of durvalumab plus olaparib in patients with metastatic pancreatic cancer and DNA damage repair genes alterations

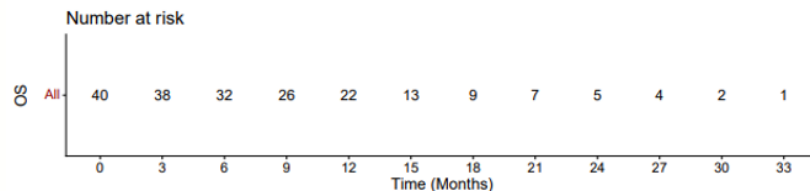
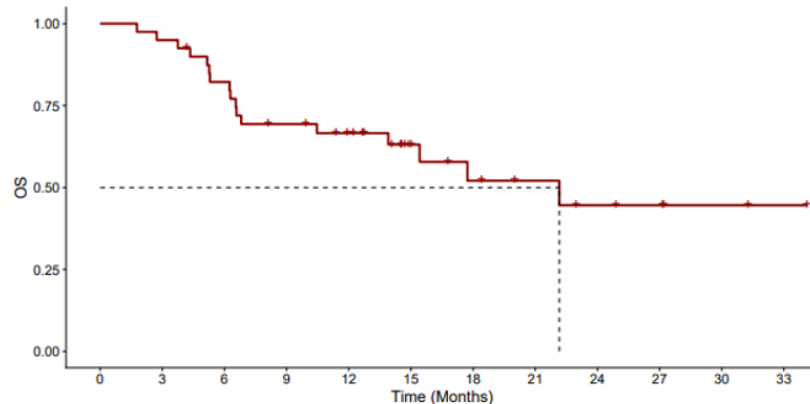
**PFS (all patients)**

Characteristic	6 months	12 months	24 months	Median (95% CI)
PFS rates (95% CI)	53% (39, 70)	38% (25, 56)	23% (11, 51)	6.7m (3.7, -)



**OS (all patients)**

Characteristic	6 months	12 months	24 months	Median (95% CI)
OS rates (95% CI)	82% (71, 95)	67% (53, 83)	45% (28, 72)	22.2m (13.9, -)





## Phase II study of durvalumab plus olaparib in patients with metastatic pancreatic cancer and DNA damage repair genes alterations

**SWOG S2001**

**NCT04548752**

gBRCA mut PDAC not  
progression to platinum  
based chemotherapy

Olaparib +  
Pembrolizumab

Olaparib



ALTOPANC: Local ablative therapies in oligometastatic PDAC-A binational french-Belgian retrospective study.

## Oligometastatic Disease (OMD) in PDAC

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### *An emerging clinical entity*



More favorable biology



Better prognosis



Rising of incidence thanks to efficacy of systemic therapies



Definition of the OMD: not consensual until now



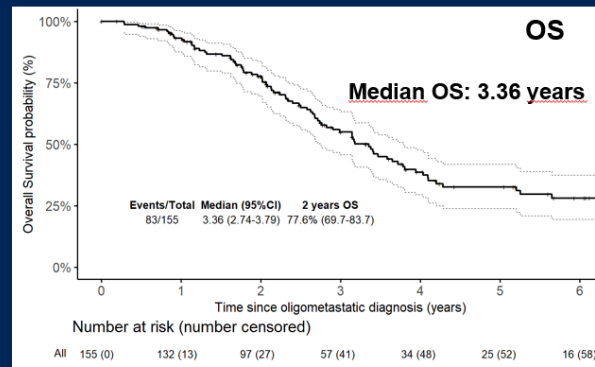
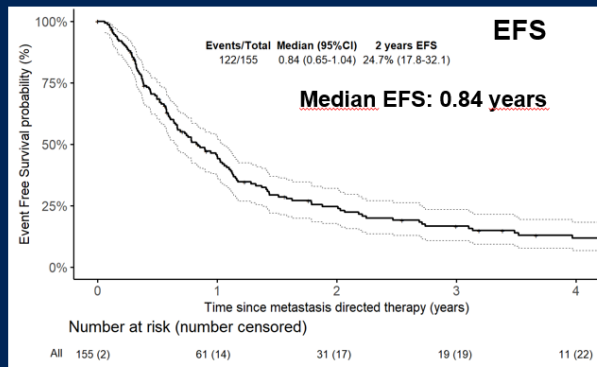
## ALTOPANC: Local ablative therapies in oligometastatic PDAC-A binational french-Belgian retrospective study.

	<u>Surgery</u> n(%)	<u>Radiotherapy</u> n(%)	<u>Radiofrequency</u> n(%)	p-value
<u>Number of metastases</u>				
1	51(77)	31 (63)	25 (71)	p = 0.38
>1	15 (23)	17 (37)	10 (29)	
<u>CA19.9 at metastatic diagnosis( median)</u>	31,5 (15-200)	64 (17-190)	33,7 (17-191)	p = 0.72
<u>Performance Status for metachronous</u>				
0	17(40)	26(55)	11(39)	p = 0.31
1	24(56)	19(41)	14(50)	
>1	2(4)	2(4)	3(11)	
<u>Median size (mm) (Q1-Q3)</u>	15 (5-350)	11 (5-35)	10 (4-120)	p = 0.11
<u>Metastatic sites</u>				
<u>Liver</u>	34(49)	22(44)	15(42)	p = 0.72
<u>Lung</u>	23(33)	16(32)	22(61)	p = 0.0095



# ALTOPANC: Local ablative therapies in oligometastatic PDAC-A binational french-Belgian retrospective study.

## Results (3) : EFS and OS in the whole cohort



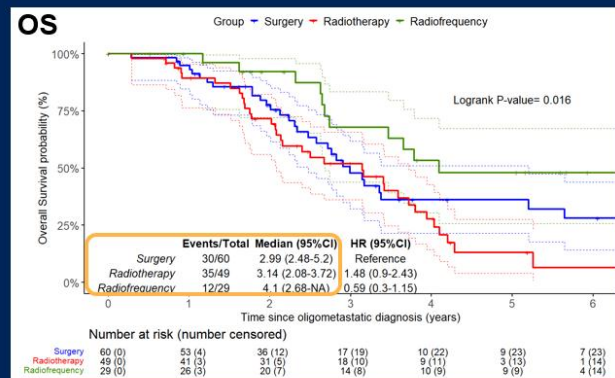
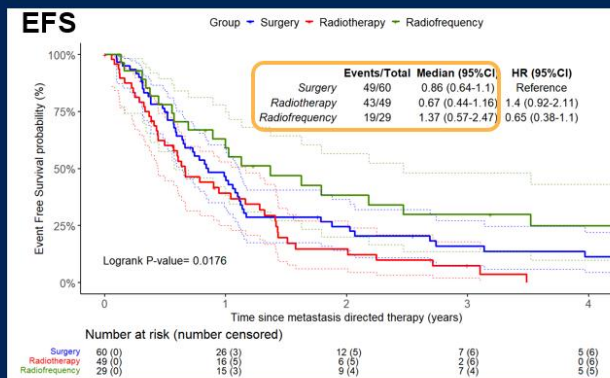
Median follow up of 4.42 years



# ALTOPANC: Local ablative therapies in oligometastatic PDAC-A binational french-Belgian retrospective study.

## Results (4) : EFS and OS in the metachronous population

Radiofrequency    Surgery    Radiotherapy



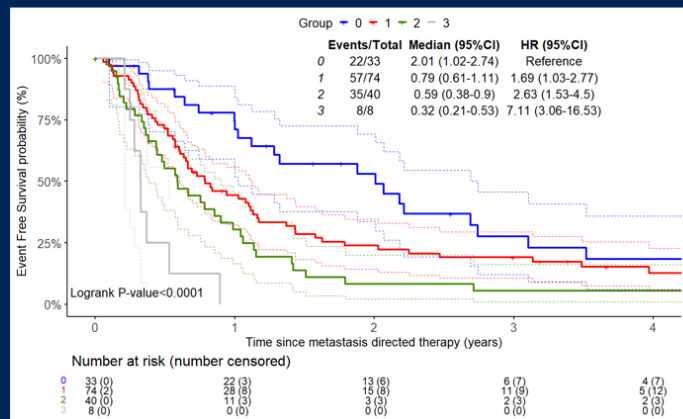
Median follow up of 4.42 years



# ALTOPANC: Local ablative therapies in oligometastatic PDAC-A binational french-Belgian retrospective study.

## Results (5) : Prognostic score (« ALTOPANC »)

- Prognostic score for EFS using prognostic factors identified in the multivariate analysis and literature
- 1 point attributed for each variable:
  - CA 19.9 serum level > 90 U/mL,
  - >1 metastases,
  - non-pulmonary site





## **Tumores biliares**

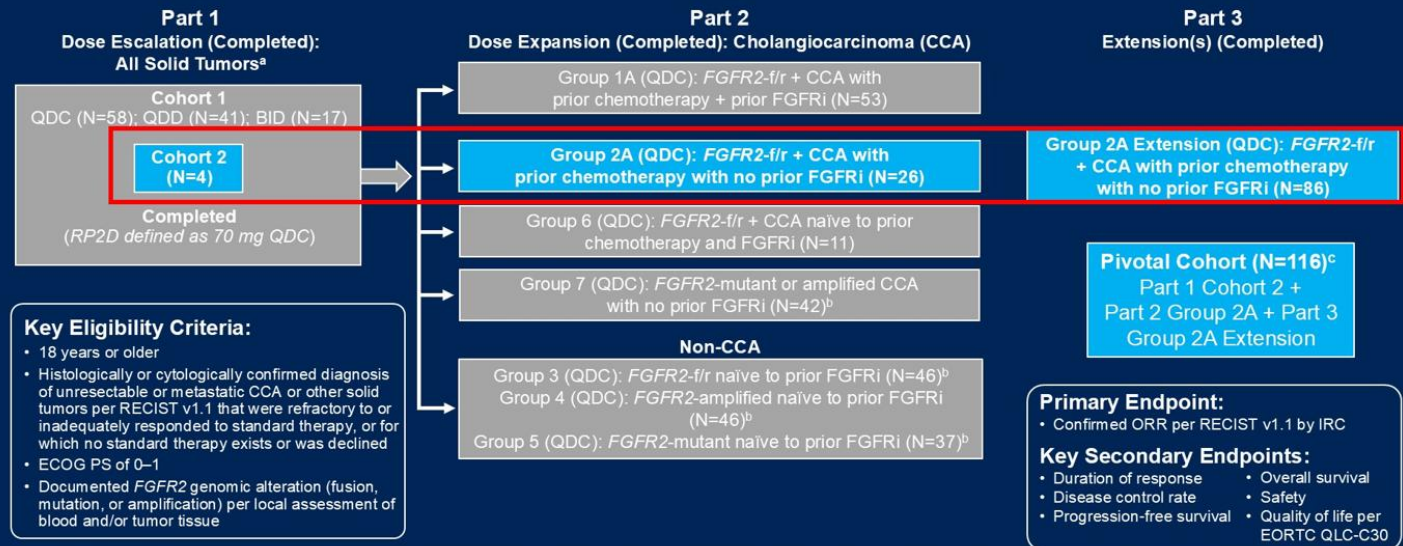
### **Oral presentation**

Eficacia and safety of lirafugratinib in FGFRi-naive CCA harboring FGFR2 fusions/rearrangements



# Eficacia and safety of lirafugratinib in FGFRi-naive CCA harboring FGFR2 fusions/rearrangements

## ReFocus: A Phase 1/2 Open Label Study (NCT04526106)



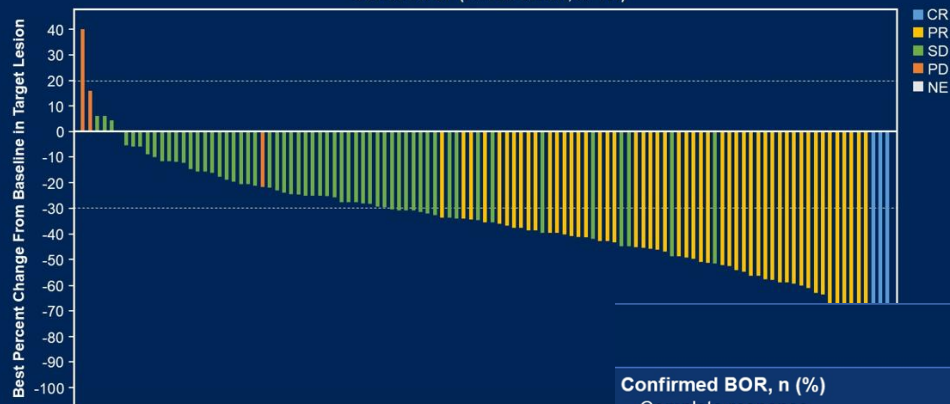
RLY4008:  
selective,  
irreversible  
FGFR2  
inhibitor

BID, twice daily; CCA, cholangiocarcinoma; ECOG PS, Eastern Cooperative Oncology Group performance status; FGFR2, fibroblast growth factor receptor 2; FGFRi, fibroblast growth factor receptor inhibitor; flr, fusion/rearrangement; mRNA, messenger RNA; QDC, once daily on a continuous dosing schedule (referred to as QD on subsequent slides); QDD, once daily on a discontinuous dosing schedule; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1; RP2D, recommended Phase 2 dose.  
<sup>a</sup>Including *FGFR2* genomic alteration (fusion, amplification, or mutation) or other potentially oncogenic *FGFR2* alterations (eg, *FGFR2* protein or mRNA overexpression) and other tumor types.  
<sup>b</sup>Additional 27 patients who received prior FGFRi were enrolled in Groups 3 (n=10), 4 (n=3), 5 (n=6), and 7 (n=6). These patients were not included in the efficacy analyses but were included in the safety analyses.  
<sup>c</sup>As of 27SEP2024, the primary efficacy analysis of IRC-assessed data (n=114) and the secondary analysis of investigator-assessed data (n=116) set was done. The primary efficacy analysis excluded 2 patients as not available.



## Waterfall Plot for BOR From Baseline by IRC (Primary Efficacy Analysis Set)

CCA f/r FN CP (Pivotal Cohort; N=114)



BOR, best overall response; CCA, cholangiocarcinoma; CP, chemotherapy pretreated; CR, complete response; FN, fibroblast growth factor receptor inhibitor evaluable; PD, progressive disease; PR, partial response; SD, stable disease.

CCA f/r FN CP  
(Pivotal Cohort; N=114)

### Confirmed BOR, n (%)

Complete response	3 (2.6)
Partial response	50 (43.9)
Stable disease	57 (50.0)
Progressive disease	3 (2.6)
Not evaluable <sup>a</sup>	1 (0.9)

ORR<sup>b</sup>, n (%) [95% CI] 53 (46.5) [37.1, 56.1]

DCR<sup>c</sup>, n (%) [95% CI] 110 (96.5) [91.3, 99.0]

Median DOR, months [95% CI] 11.8 [7.5, 13.0]

Median PFS, months [95% CI] 11.3 [9.2, 14.8]

Median OS<sup>d</sup>, months [95% CI] 22.8 [18.1, 27.2]



## Summary of On-Target TEAEs (Safety Analysis Set)

	All Solid Tumors (70 mg QD Safety Population; N=385)		CCA f/r FN CP (Pivotal Safety Population; N=116)	
	Any Grade	Grade $\geq 3$	Any Grade	Grade $\geq 3$
Stomatitis <sup>a</sup> , n (%)	263 (68.3)	47 (12.2)	91 (78.4)	14 (12.1)
Palmar-plantar erythrodysesthesia syndrome, n (%)	255 (66.2)	77 (20.0)	95 (81.9)	38 (32.8)
Nail toxicities <sup>b</sup> , n (%)	282 (73.2)	31 (8.1)	102 (87.9)	14 (12.1)
Retinal pigment epithelial detachment <sup>c</sup> , n (%)	113 (29.4)	7 (1.8)	43 (37.1)	2 (1.7)



## Multicenter real-world study: a comprehensive characterization of biliary tract cancer epidemiology in Spain



1756 patients



40 hospitals

Variable	N = 1,756 <sup>1</sup>
Age at primary tumor diagnosis [median (Q1, Q3)]	68.6 (61.2, 74.9)
Sex (female)	978 (55.7%)
Location of primary tumor	
Intrahepatic	931 (53.0%)
Gallbladder carcinoma	272 (15.5%)
Extrahepatic distal	253 (14.4%)
Extrahepatic hilar	226 (12.9%)
Ampulla of Vater	47 (2.7%)
Other	27 (1.5%)
Chemotherapy	1586 (90.3%)
Immunotherapy	188 (10.7%)
Targeted therapy	111 (6.3%)
Clinical trial	136 (7.7%)

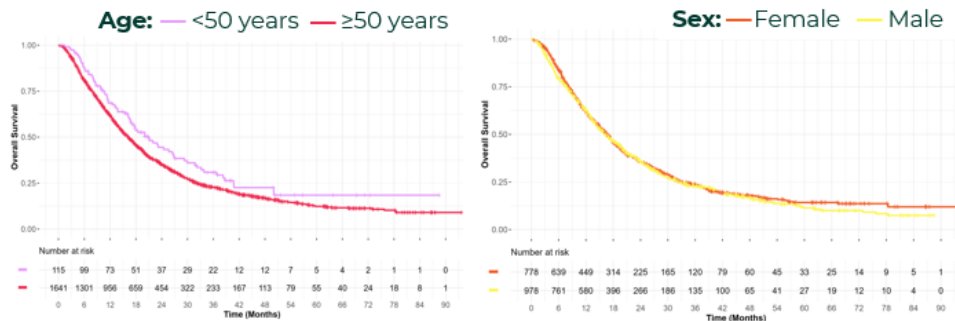


### Biomarker information: Frequent ESCAT-I alterations

ESCAT-I	Biomarker determination (N)	Alteration [N (%)]
IDH1 mutation	447	75 (16.8%)
FGFR2 fusion	401	32 (8.0%)
MSI	491	30 (6.1%)
HER2 ampl./overexpression	449	25 (5.7%)



### Overall Survival by Subgroups



Ampl., amplification; ESCAT, ESMO Scale for Clinical Actionability of Molecular Targets; MSI, microsatellite instability; RETUD, Registro Español de Tumores Digestivos

1. Macarulla et al. J Clin Oncol. 2026; 44(2\_suppl): DOI: 10.1200/JCO.2026.44.2\_suppl.503



## **Tumores HCC**

### **Oral presentation**

-Adjuvant pembrolizumab for patients with HCC and complete radiological response after surgical resection or local ablation. Phase 3 Keynote 937 study

-INKF/ABC-HCC: A phase IIIb, randomized, multicenter, open-label trial of atezolizumab plus bevacizumab versus TACE in intermediate-stage HCC

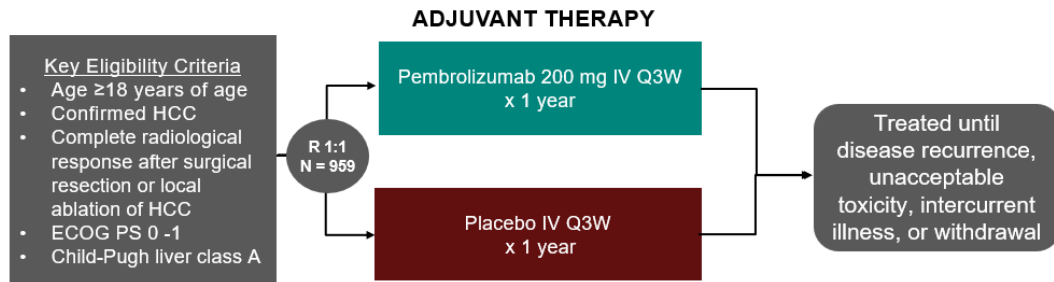
### **Rapid oral abstract presentation**

Nivolumab plus ipilimumab vs lenvatinib or sorafenib as a first line treatment for unresectable HCC: 4 years follow-up of CheckMate 9DW.



# Adjuvant pembrolizumab for patients with HCC and complete radiological response after surgical resection or local ablation. Phase 3 Keynote 937 study

## Phase 3 KEYNOTE-937 Study Design



### Stratification factors

- Region (Asia [not including Japan] vs non-Asia)
- Prior local therapy (resection vs ablation)
- Risk of recurrence (intermediate vs high vs very high risk)
- AFP at initial diagnosis before resection or ablation (<200 ng/mL vs ≥200 ng/mL)

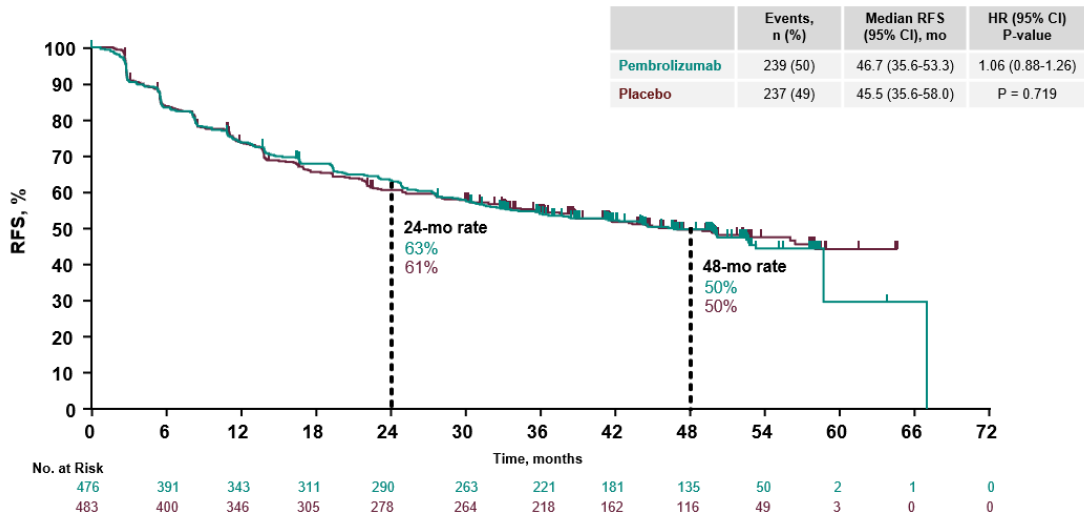
### Endpoints

- Primary: RFS by BICR or pathology; OS
- Key secondary: DMFS by BICR or pathology, safety



# Adjuvant pembrolizumab for patients with HCC and complete radiological response after surgical resection or local ablation. Phase 3 Keynote 937 study

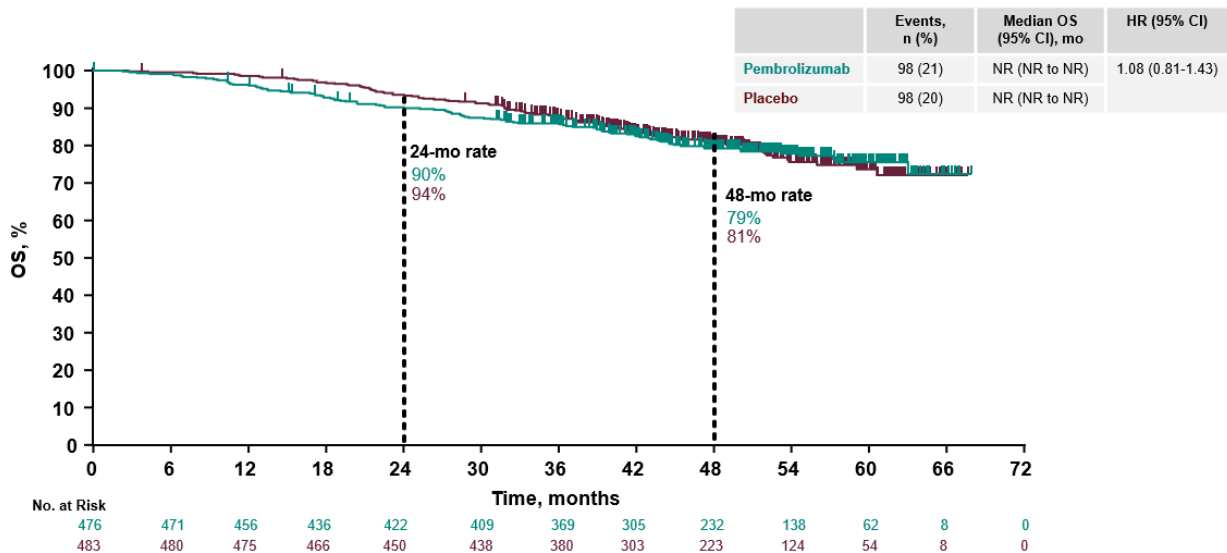
## Recurrence-Free Survival





# Adjuvant pembrolizumab for patients with HCC and complete radiological response after surgical resection or local ablation. Phase 3 Keynote 937 study

## Overall Survival





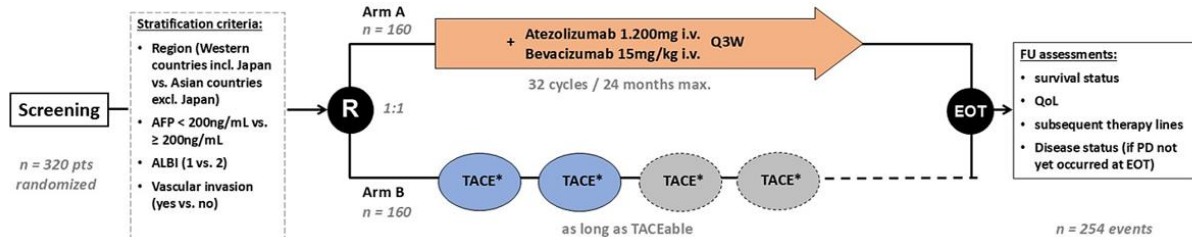
# INKF/ABC-HCC: A fase IIIb, randomized, multicenter, open-label trial of atezolizumab plus bevacizumab versus TACE in intermediate-stage HCC

## IKF-035/ABC-HCC Study Design

an international, randomized, multicenter, open-label, investigator-initiated phase 3b trial

6

Screening -----> Stratification -----> Randomization -----> Treatment phase (either systemic drug treatment OR locoregional therapy)<sup>§</sup> -----> Follow-Up



<sup>§</sup> Patients will be treated until loss of clinical benefit, development of unacceptable toxicity, participant request, or withdrawal of consent (whatever first).

\* Both conventional TACE (c-TACE) and drug-eluting beads (DEB-TACE) approaches are accepted. However, each study site is required to maintain consistency in the TACE procedure and the use of doxorubicin or epirubicin as a chemoembolization agent throughout the study duration.



# INKF/ABC-HCC: A fase IIIb, randomized, multicenter, open-label trial of atezolizumab plus bevacizumab versus TACE in intermediate-stage HCC

## Primary endpoint

allowing a fair comparison between two modalities (systemic Tx vs. locoregional Tx)

### Time to failure of treatment strategy (TTFS)

Failure of strategy =

**Arm A (Atezo/Bev)**

**Arm B (TACE)**

1<sup>st</sup> condition



radiologic progression

radiologic progression  
or stable disease

2<sup>nd</sup> condition

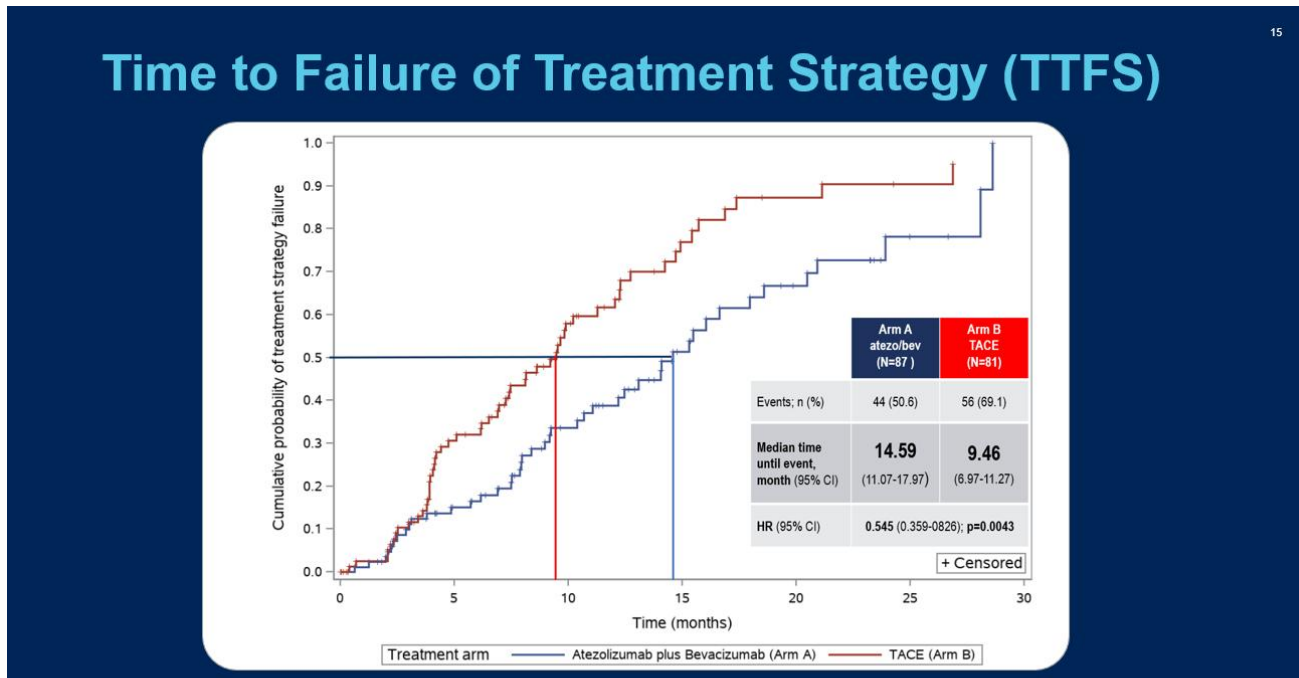


AND any of the following:

- the loss of clinical benefit OR
  - Progression at critical anatomical sites
  - Development of symptoms and signs (including laboratory values) unequivocal progression of disease
  - Decline in ECOG performance status attributed to disease progression
  - No evidence of clinical benefit as assessed by the investigator
- unacceptable toxicity OR
- liver function deterioration OR
- therapy not further applicable for other reasons



# INKF/ABC-HCC: A fase IIIb, randomized, multicenter, open-label trial of atezolizumab plus bevacizumab versus TACE in intermediate-stage HCC



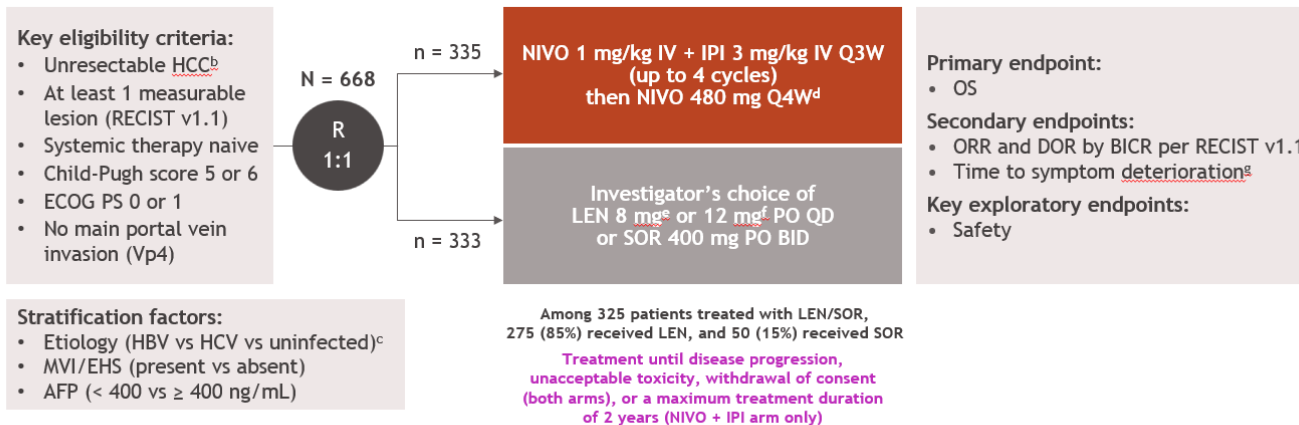


# Nivolumab plus ipilimumab vs lenvatinib or sorafenib as a first line treatment for unresectable HCC: 4 years follow-up of CheckMate 9DW.

CheckMate 9DW

## CheckMate 9DW study design

- CheckMate 9DW is a global, phase 3, randomized, open-label trial of NIVO in combination with IPI compared with LEN or SOR as 1L treatment in patients with unresectable HCC<sup>a</sup>



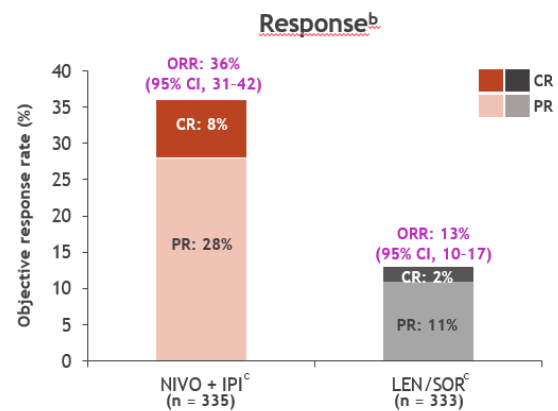
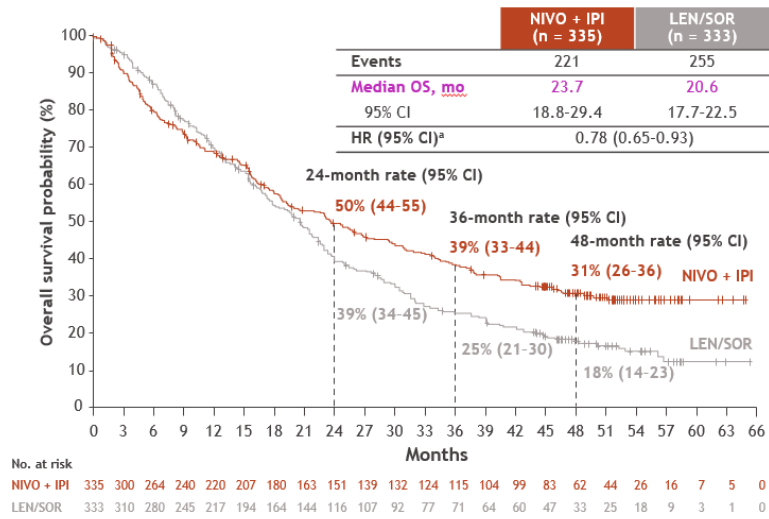
- At data cutoff (July 9, 2025), median (range) follow-up<sup>h</sup> was 52.5 (44.0-66.1) months



# Nivolumab plus ipilimumab vs lenvatinib or sorafenib as a first line treatment for unresectable HCC: 4 years follow-up of CheckMate 9DW.

CheckMate 9DW

## Overall survival, response, and duration of response



Median TTR (range), <sup>d</sup> mo	2.2 (1.1-41.7)	3.7 (0.6-8.0)
Median DOR (95% CI), <sup>d</sup> mo	34.3 (22.6-47.7)	12.9 (10.2-33.9)
Patients with DOR ≥ 48 mo, <sup>d</sup> % (95% CI)	37 (24-50)	12 (1-38)

- Sustained OS benefit with NIVO + IPI vs LEN/SOR with longer follow-up, and higher 48-month OS rates
- Continued ORR benefit with NIVO + IPI vs LEN/SOR, with a higher CR rate and durable responses

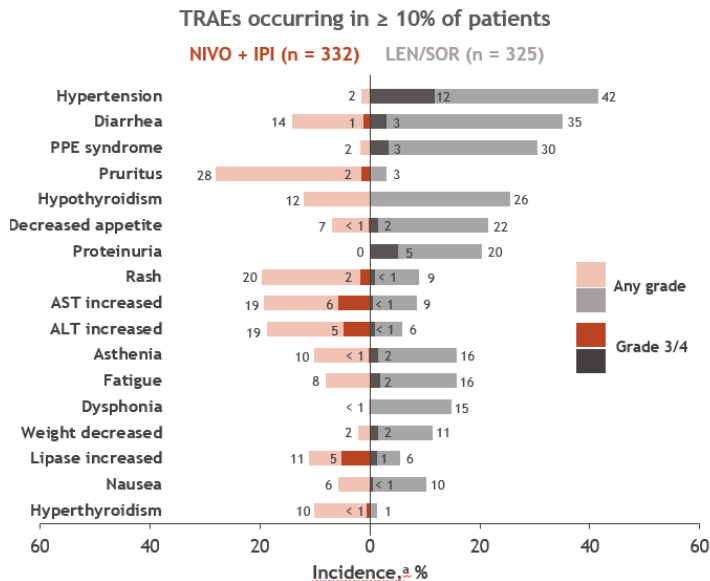


# Nivolumab plus ipilimumab vs lenvatinib or sorafenib as a first line treatment for unresectable HCC: 4 years follow-up of CheckMate 9DW.

## Safety summary

	NIVO + IPI (n = 332)	LEN/SOR (n = 325)
All treated patients, n (%)		
Median (range) duration of treatment, mo	4.7 (< 0.1 to 24.4)	6.9 (< 0.1 to 50.6)

All treated patients, n (%)	NIVO + IPI (n = 332)		LEN/SOR (n = 325)	
	Any grade	Grade 3/4	Any grade	Grade 3/4
<b>TRAEs<sup>a</sup></b>				
Any TRAEs	277 (83)	136 (41)	297 (91)	138 (42)
Serious TRAEs	94 (28)	83 (25)	47 (14)	42 (13)
TRAEs leading to discontinuation	59 (18)	44 (13)	34 (10)	21 (6)
<b>Treatment-related deaths<sup>b</sup></b>	12 (4) <sup>c</sup>		3 (< 1) <sup>d</sup>	



- Safety was consistent with previous follow-up,<sup>1</sup> with no new safety signals

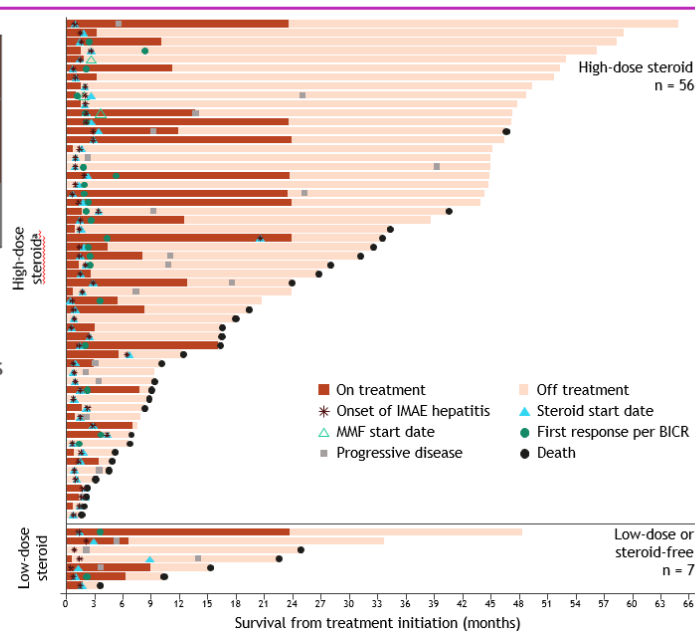


# Nivolumab plus ipilimumab vs lenvatinib or sorafenib as a first line treatment for unresectable HCC: 4 years follow-up of CheckMate 9DW.

## Immune-mediated hepatitis with NIVO + IPI

All NIVO + IPI treated patients, n (%)	NIVO + IPI (n = 332)			
	Any grade	Grade 3/4	Received high-dose steroids <sup>a</sup>	Leading to D/C
Hepatitis IMAEs <sup>b</sup>	63 (19)	51 (15)	56 (17)	19 (6)

- Median time to onset of any-grade immune-mediated hepatitis was 6.0 (range, 0.9-88.9) weeks; these events resolved in 47 of 63 (75%) patients with a median time to resolution of 10.3 (range, 0.9-129.3+) weeks
- Hepatitis IMAEs continued to be manageable using established algorithms and most did not result in treatment discontinuation





*Muchas gracias por su atención*  
*macarulla@clinic.cat*