2025 John Hopkins Updates in Gastrointestinal Cancers

Management of Advanced Pancreas Cancer

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Memorial Sloan Kettering Cancer Center

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Consulting/Data & Safety Monitoring Boards/Steering Committees

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Family: Agios, Genentech-Roche, Eisai, Servier, Abbvie

Off Label/Investigational Use

Pembrolizumab, nivolumab, ipilimumab, sotigalimab, zenocutuzumab, nimotuzumab, zolbetuximab, autogene cevumaren, MRG004A

Agenda

Current standards

KRAS Wild-Type

DNA damage repair-directed therapy

Immunotherapy

Other targets in PDAC

Current State of Therapy Advanced PDAC 2024

First & Second-Line Practice-Changing Phase III Trials for Unselected Disease

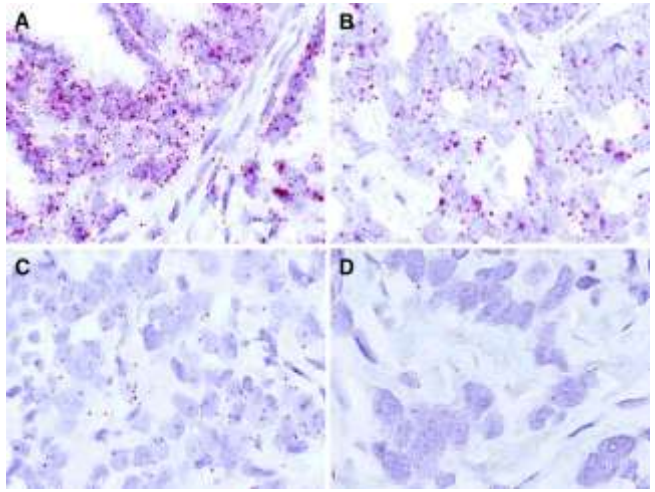
	N	Median OS	Median PFS	Response Rate	Reference
First-Line					
mFOLFIRINOX (vs Gem) PRODIGE/ ACCORD 11	171	**11.1 m**	6.4 m	31.6%	2011
Gemcitabine, nab-Paclitaxel (vs Gem) MPACT	431	**8.5 m**	5.5 m	23%	2013
NALIRIFOX (vs Gem/Nab-P) NAPOLI-3	383	**11.1m**	7.4 m	41.8%	2024
Second-Line					
Liposomal irinotecan/5-FU vs 5-FU NAPOLI-1	117	**6.1 m**	3.1 m	16%	2016

Conroy T. N Engl J Med. 2011
Von Hoff, D. NEJM, 2013
Wainberg, Z. Lancet, 2023
Wang-Gillam, A. Lancet Oncol, 2016

Subytpe PDAC: COMPASS Non-Randomized, Met 1st Line

Opportunity for Therapy Selection?

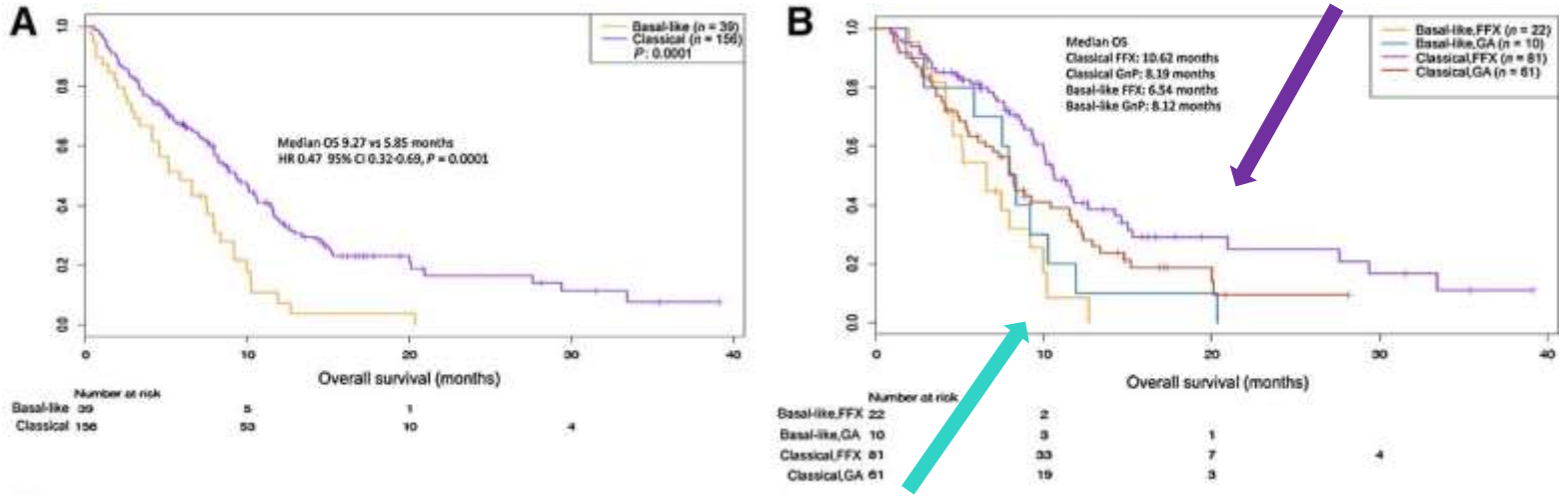
Panels A, B: Classical Moffit



Panels C, D: Basal-type

Overall Survival **Classical** vs **Basal**

FOLFIRINOX (classical)



FOLFIRINOX (basal)

Med OS 9.3m **Classical** vs 5.9m **Basal**, HR 0.47, p= 0.0001

GATA6 expression RNA ISH: Biomarker for classical vs basal and outcomes

Aung, KL…Gaillinger, S. Clin Can Res, 2018
O'Kane, GM…Knox, JJ. Clin Can Res, 2020

PASS-01 Trial: Rand Phase II Advanced PDAC

Pancreatic Adenocarcinoma Signature Stratification for Treatment

Untreated Metastatic PDAC

ECOG 0-1

No g*BRCA12, PALB2*

mFOLFIRINOX
N= 75

Gemcitabine/nab-P
N= 75

Correlative Science
WGS/WES (PMH/OICR)
RNAseq (PMH/OICR)
Organoid (Cold Spring H)
ctDNA (Dana Farber)
Circulating tumor cells (MSK)
Immune (JHU)

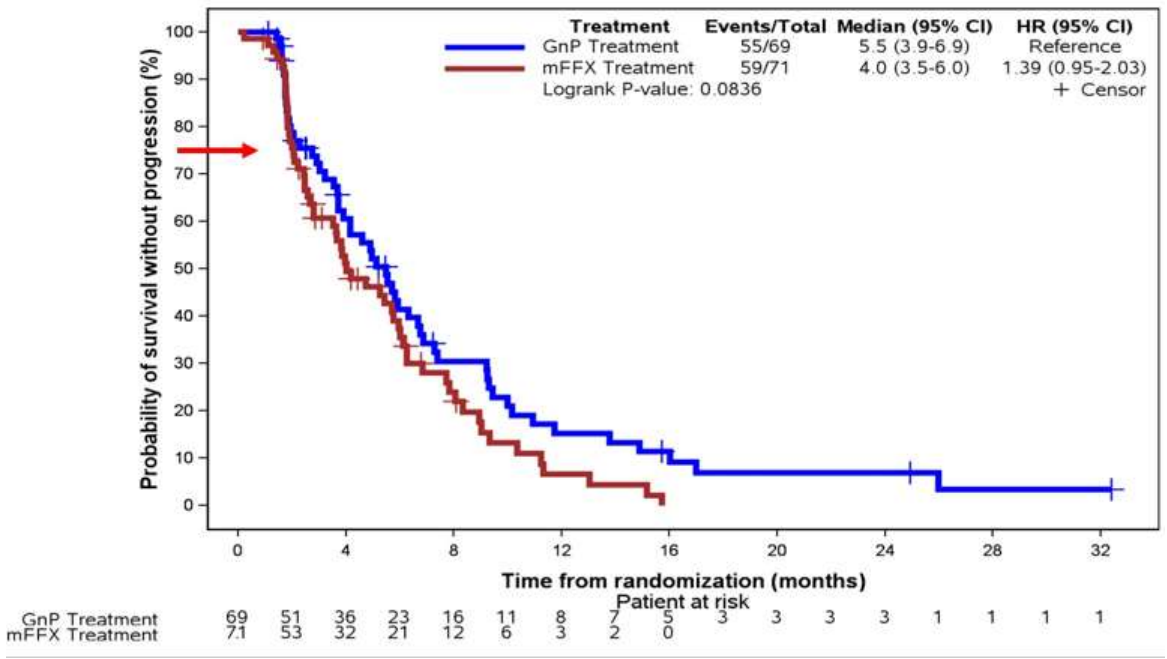
Randomization 1: 1
Primary: PFS superiority of mFFX over Gem/nabP (mFFX 7m, Gem/nab-P 5m; HR 0.7; 80% power)
Secondary: OS, RR, GATA6 (ISH, IHC)

NCT04469556 Knox, J, Jaffee, E (Co-PI's) NCT0447290
Yu, K (PI MSK)

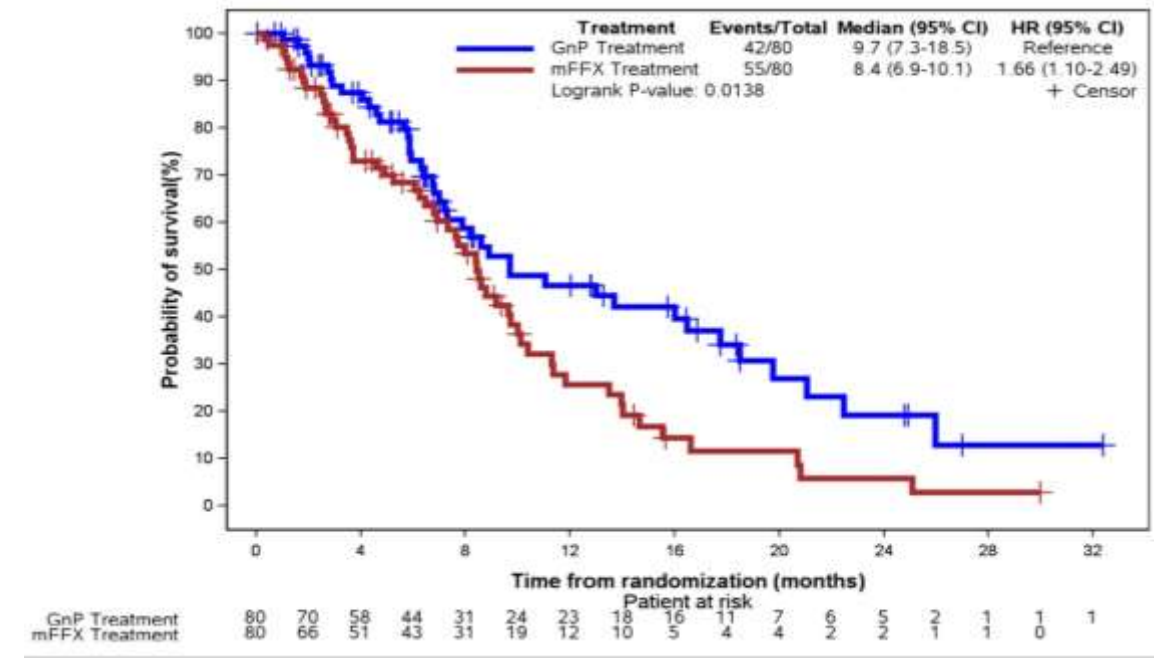
PASS-01: mFOLFIRINOX vs Gem/nab-Paclitaxel (N= 160)

First-Line Metastatic PDAC (unselected)

Primary: Progression-Free Survival



Secondary: OS (early)

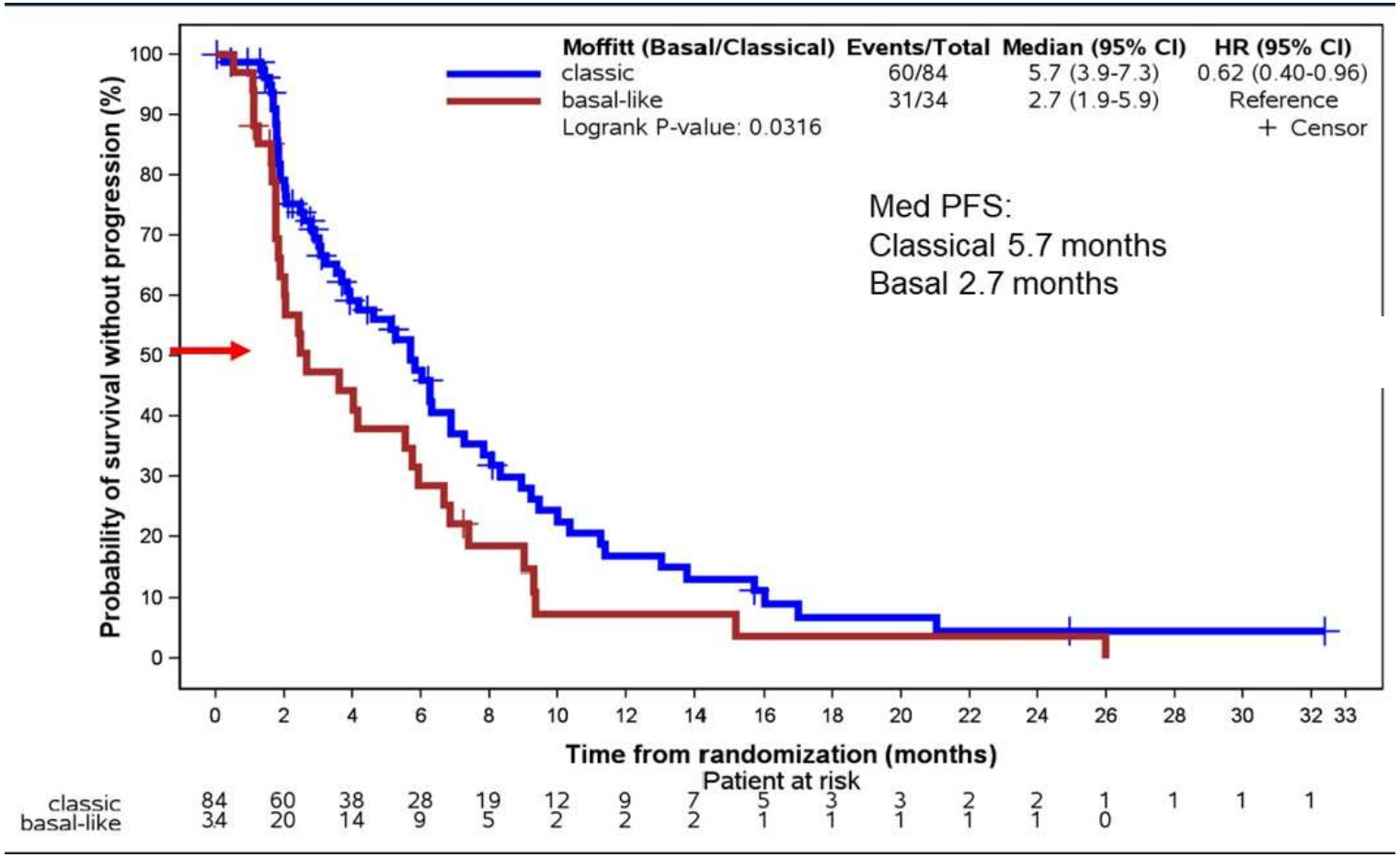


*Excludes g*BRCA1/2, PALB2*; includes only de novo metastatic (biopsiable) disease, imbalance *KRAS*^{WT}

- PASS-01 favors gemcitabine/nab-P…
- More equipoise for drug development backbones

Knox, JJ. Jaffee, EM, O'Kane, GM…..Gallinger, S, Tuveson, DA. ASCO, 2024

PASS-01: Classical, Basal Subtypes Prognostic in PDAC



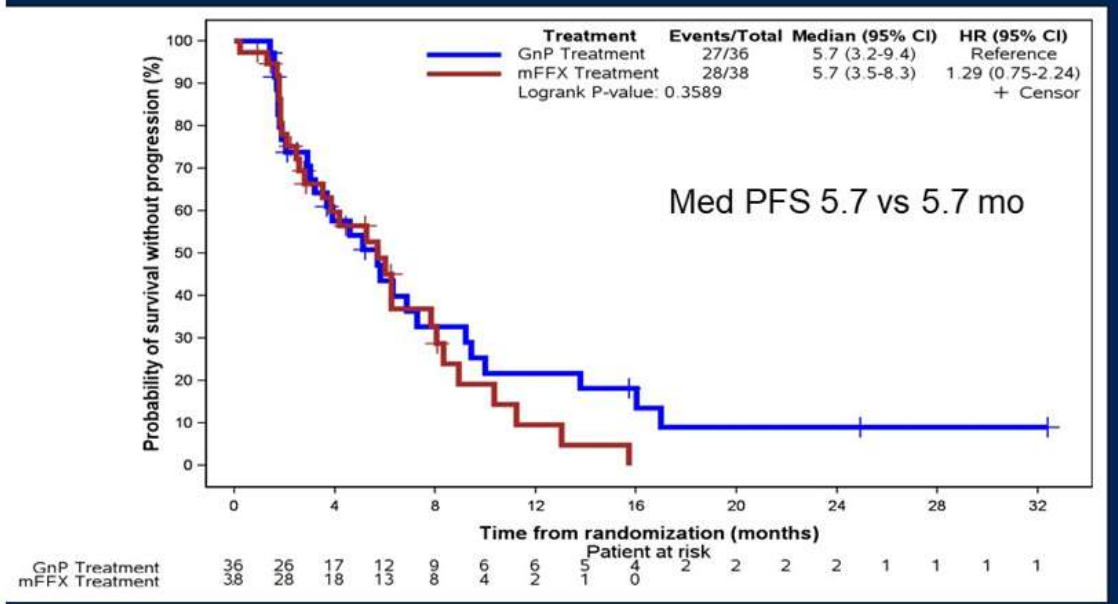
- Increasing evidence for molecular subtypes to inform therapy in PDAC

Knox, J…Jaffee, E. ASCO, 2024

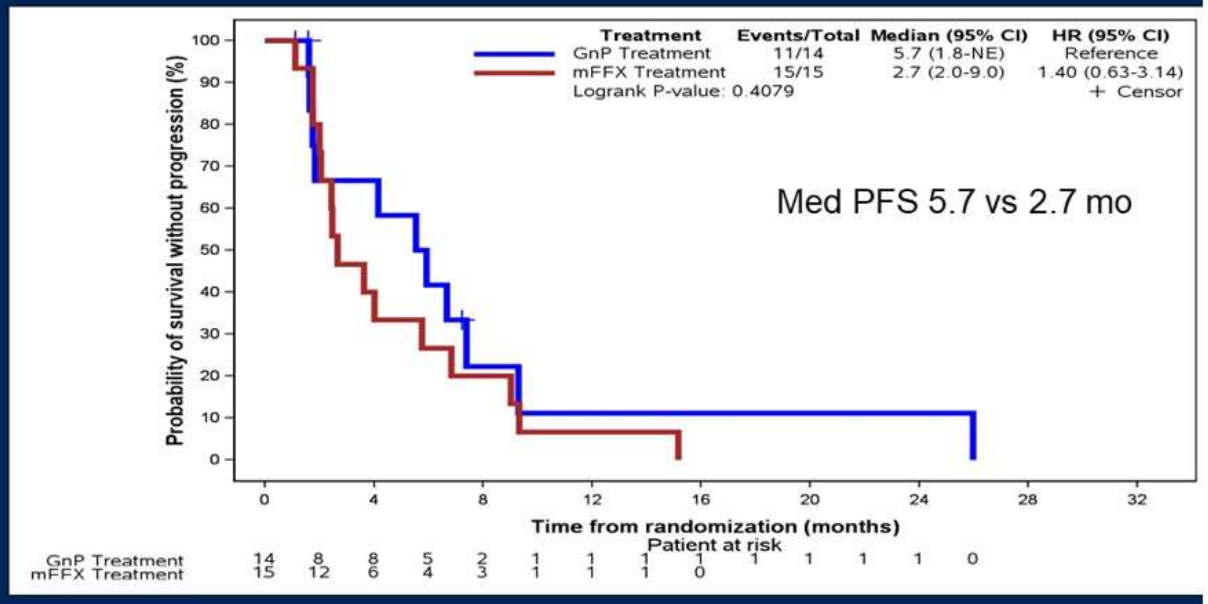
PASS-01: Differential Treatment Response

Therapy Selection 2025?

Classical Sub-Type



Basal Sub-Type

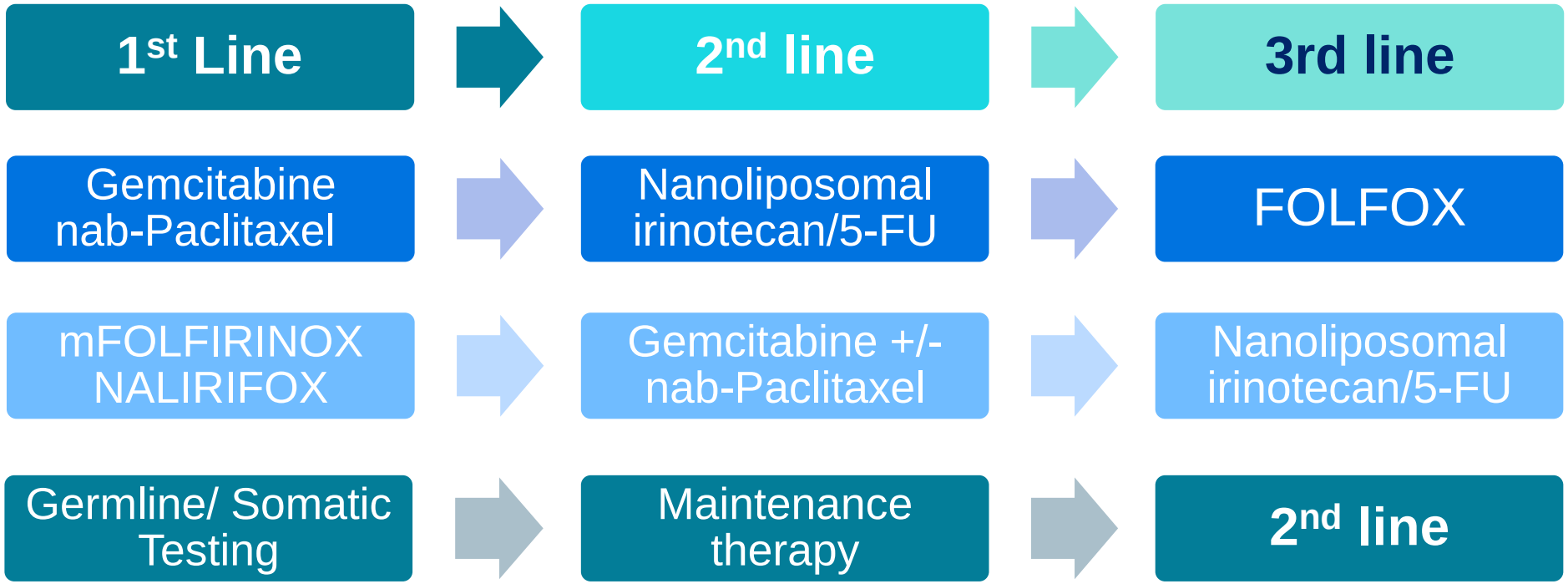


Blue: GnP, Red: mFFX

Knox, J…Jaffee, E. ASCO, 2024
Aung, KL. Clin Can res, 2018
O'Kane, GM. Clin Can Res, 2020

2025 John Hopkins Updates in Gastrointestinal Cancers

Sequencing Therapy in Advanced PDAC 2025



Adapted NCCN Guidelines 2024

EXTEND Trial: Rand Phase II SOC +/- Metastasis-Directed Therapy (MDT) for Oligometastatic Pancreas Cancer

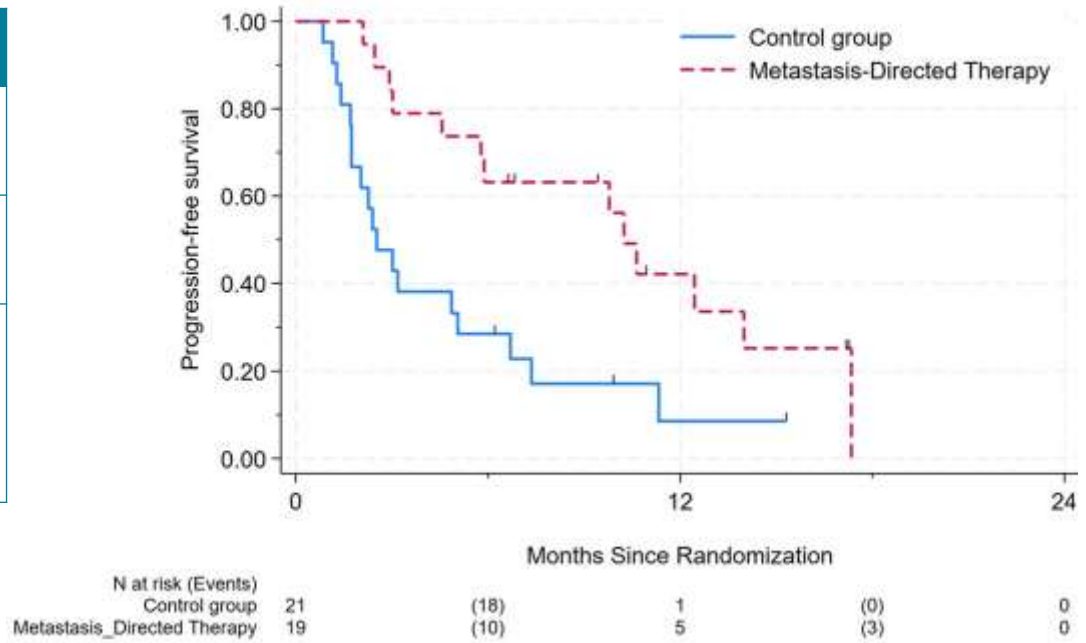
EXTEND: EXTernal beam Radiation to Eliminate Nominal Metastatic Disease

Stratify: Mets 1-2 vs 3-5; Lines of therapy 0-1 vs ≥ 2; Ca 19-9 <90 vs ≥ 90
Primary endpoint: median PFS (~N= 40; HR 0.47)
Secondary endpoint: median OS

Ludmir, E. Gastrointestinal Cancers Symposium, 2024
Ludmir, E. J Clinical Oncol, 2024

EXTEND Trial: Rand Phase II SOC +/- Metastasis-Directed Therapy (MDT) for Oligometastatic Pancreas Cancer

	SOC + MDT	SOC	Statistic
Med PFS	10.3 m	2.5 m	HR 0.43 (0.2- 094), p= 0.03
Med OS	12 m	10 m	HR 0.25 (0.25- 0.21), p= 0.21
Exploratory	CD8+ T cells PD1+ T cells CD25+ T cells IL-15		All significant in SOC + MDT arm



Ludmir, E. Gastrointestinal Cancers Symposium, 2024
Ludmir, E. J Clin Oncol, 2024

Genomic Subsets for Therapeutic Actionability: 2025

Increasing Biomarker Selected Options for PDAC

KRAS^{MUT} PDAC (~95%)

Chemotherapy
mFOLFIRINOX
NALIRIFOX
Gemcitabine, nab-Paclitaxel
Gemcitabine, Erlotinib

***KRAS* Therapies**
G12C Sotorasib, Adagrasib
+ other alleles: Pending

BRCA1/2, PALB2
Platinum therapy
PARPi: Olaparib, Rucaparib

KRAS^{WT} PDAC (~5%)

Fusions
RET ALK, ROS, NTRK FGFR2/3, MET, NRG-1*
Selperactinib, Entrectinib, Larotrectinib, **Zenocutuzumab**

***BRAF* V600E^{MUT}**
Dabrafenib, Encorafenib

***KRAS*^{WT}**
Erlotinib

HER2/ERBB2(+)
Trastuzumab deruxtecan

HRD, MSI-H

Mismatch Repair Deficiency
TMB >10
Nivolumab, Pembrolizumab, Dostarlimab

BRCA1/2, PALB2
Platinum therapy
PARPi: Olaparib, Rucaparib

Acinar cancer

Other Targets, Descriptors

Surface Tropisms
Claudin 18.2
Tissue factor

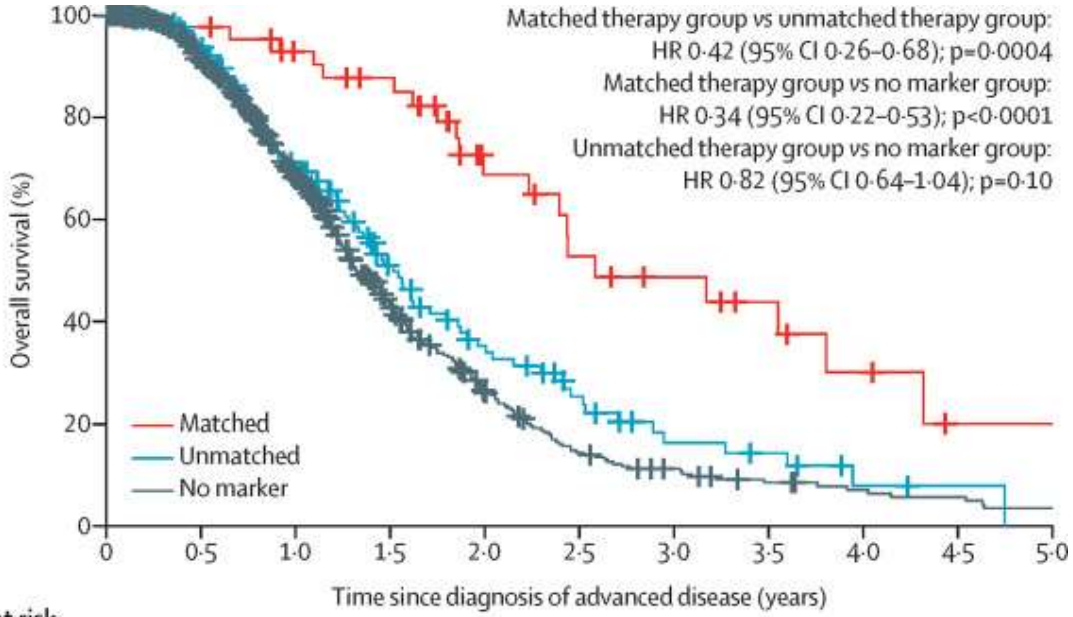
Classical, Basal
GATA6
GEMPRED

Germline (multigene), Somatic (+/-ctDNA) testing

All referenced drugs either FDA approved, guideline endorsed

Targeted Therapeutics May Improve Outcomes in PDAC

Hints for Subsets of Patients



Number at risk (number censored)											
Matched therapy	46	42	36	32	18	13	10	7	4	1	1
	(0)	(3)	(4)	(2)	(8)	(1)	(2)	(2)	(1)	(2)	(0)
Unmatched therapy	143	116	78	44	27	16	8	6	2	1	0
	(0)	(19)	(11)	(15)	(4)	(4)	(3)	(1)	(2)	(1)	(0)
No marker	488	384	241	124	63	33	22	14	10	8	5
	(0)	(66)	(55)	(39)	(15)	(4)	(4)	(3)	(2)	(0)	(0)

- **Genomic alteration and matched therapy in PDAC improve outcome**

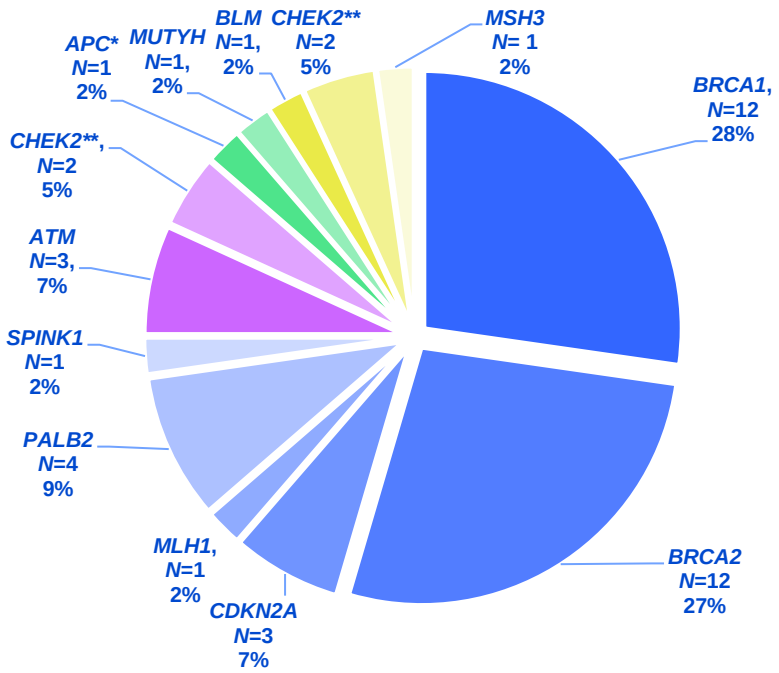
(retrospective, non-randomized)

Pishvaian, M. Lancet Oncology. 2020
Reissig, TM.…Siveke, JT. ESMO Open, 2023

KRAS Wild-Type PDAC

Early Onset Pancreas Cancer: Germline & *KRAS* Status

N= 450 ≤ 50 years



KRAS	N	Percent
KRAS Alterations	110	**83%**
***RAS* wild-type**	**21**	**16%**

Early onset PDAC (< 55 years)

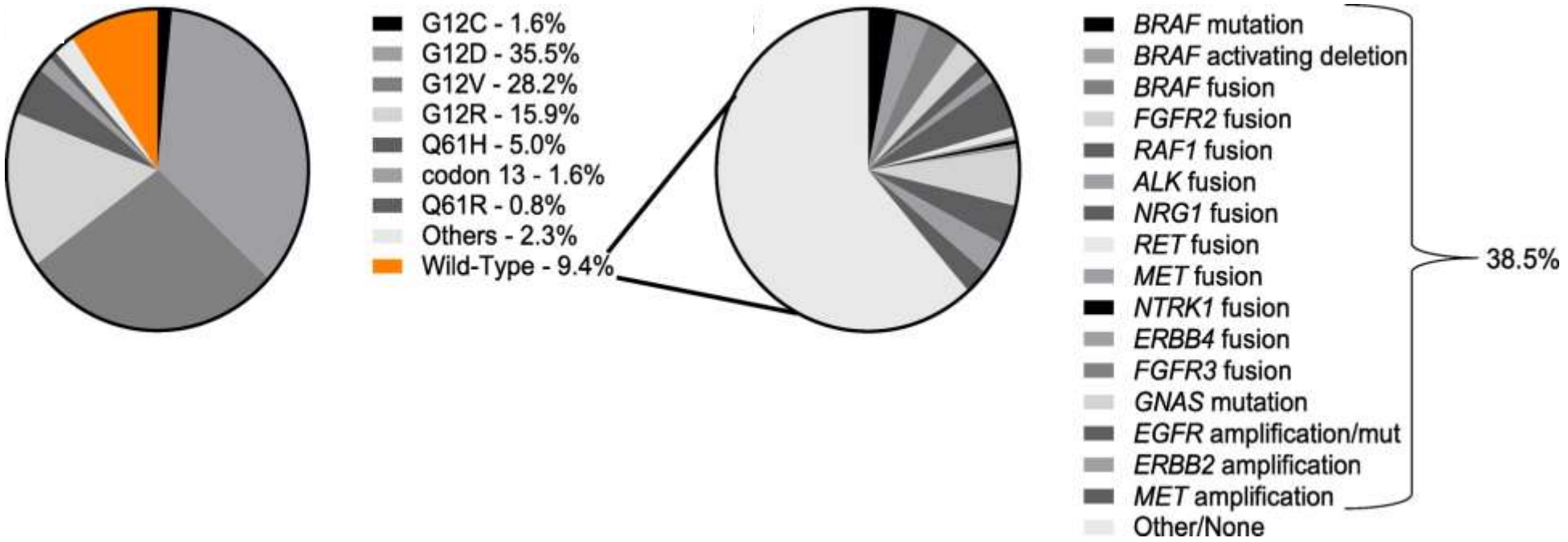
- More likely to be *KRAS*^{WT} (15-20%)
- More likely to have germline alteration

32% (44/138) Genetic predisposition

Varghese, A... O'Reilly, EM. J Nat Can Inst, 2021
Singhi, AD. Gastroenterology, 2019
Varghese, A, Perry, M…O'Reilly, Nat Med, 2025

Early Onset PDAC: *KRAS*^{WT} PDAC (~5-8%)

Rare but Important Oncogenic Drivers beyond *RAS*

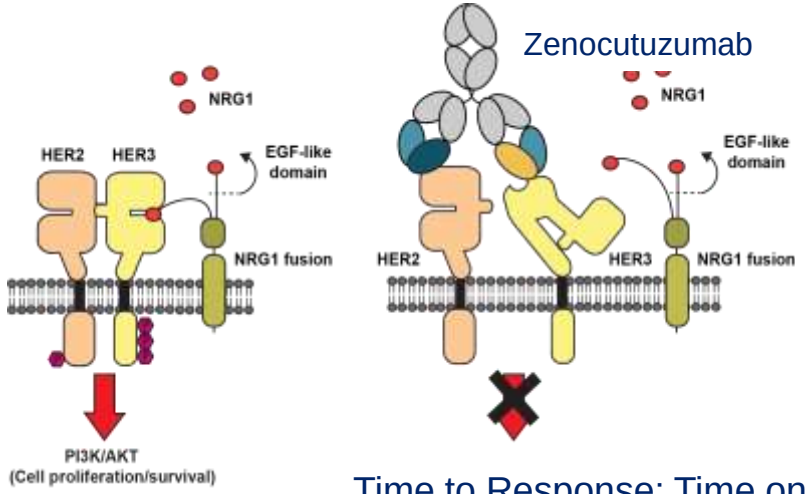


Lee, MS, Pant, S. ASCO Educational Book, 2021
Philip, P. Clin Can Res, 2022
Singh, H. Clin Can Res, 2023
Varghese, A.. JNCI, 2021
Singhi, AD. Gastroenterology, 2019
Varghese, A. Nat Med, 2025

Zenocutuzumab: Bispecific Ab Targets HER2/HER3

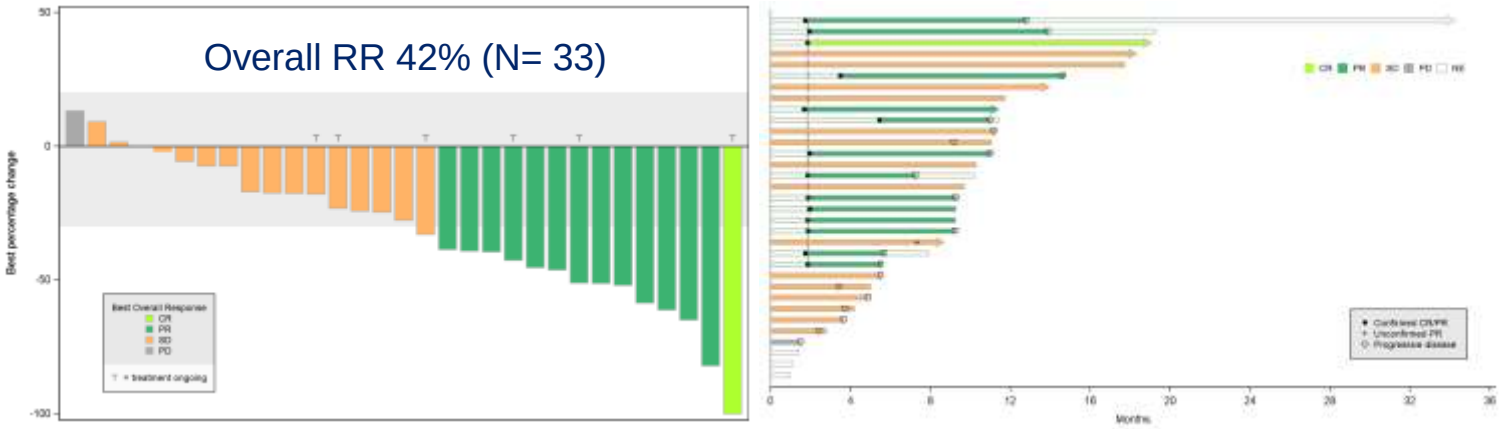
*NRG*1 Fusion(+) PDAC

- Neuregulin 1 (*NRG*1) ligand binds HER3 → HER2/HER3 heterodimerization, oncogenesis
- Zenocutuzumab binds extracellular domains HER2, HER3, blocks anti-tumor activity; ADCC



- *NRG*1(+) PDAC (N= 33)
  - ORR 42% (39% PR; 3% CR)
  - Tumor reduction 82%
  - Med duration response 9.1 m
  - FDA approval 12 2024
    - *NRG*1(+) NSCLC, PDAC

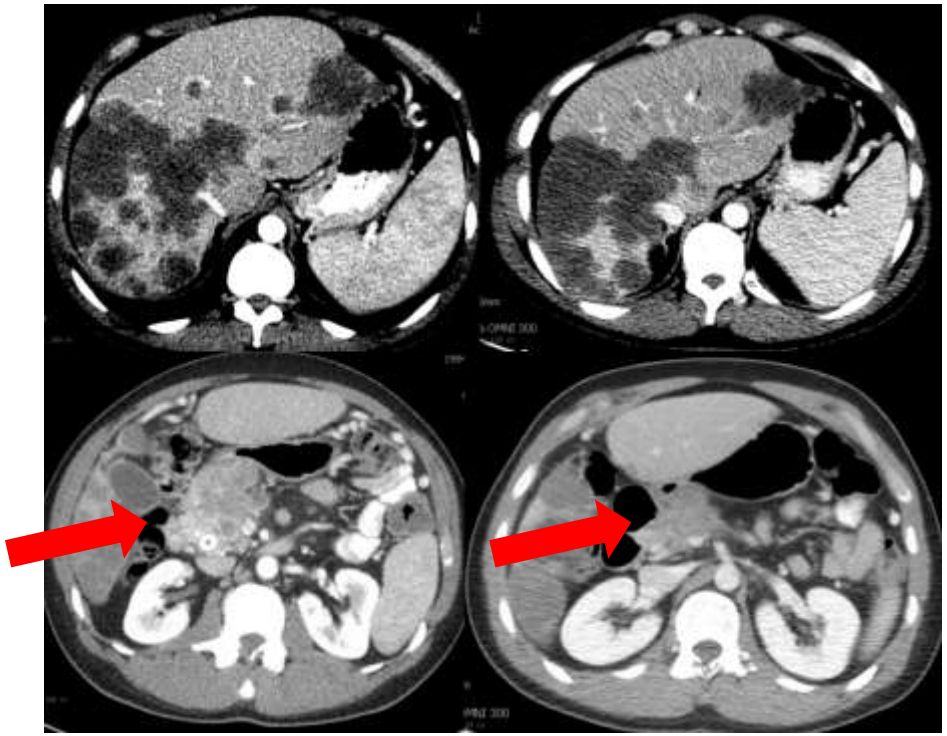
Time to Response; Time on Therapy



Schram, A……O'Reilly, EM. ESMO, 2023
Schram, A….Drilon, A. N Eng J Med, 2025

Young Man PDAC *KRAS*-WT *NRG1(+)* Fusion

Bispecific, IgG1 mAb ADCC inhibits HER2, HER3



Baseline
Ca 19-9 ~450

T+ 2 m
Ca 19-9 <50

Features *NRG*1(+) PDAC Tumors

Younger patients/ early onset PDAC
KRAS wild-type
Low Ca 19-9, disease bulk

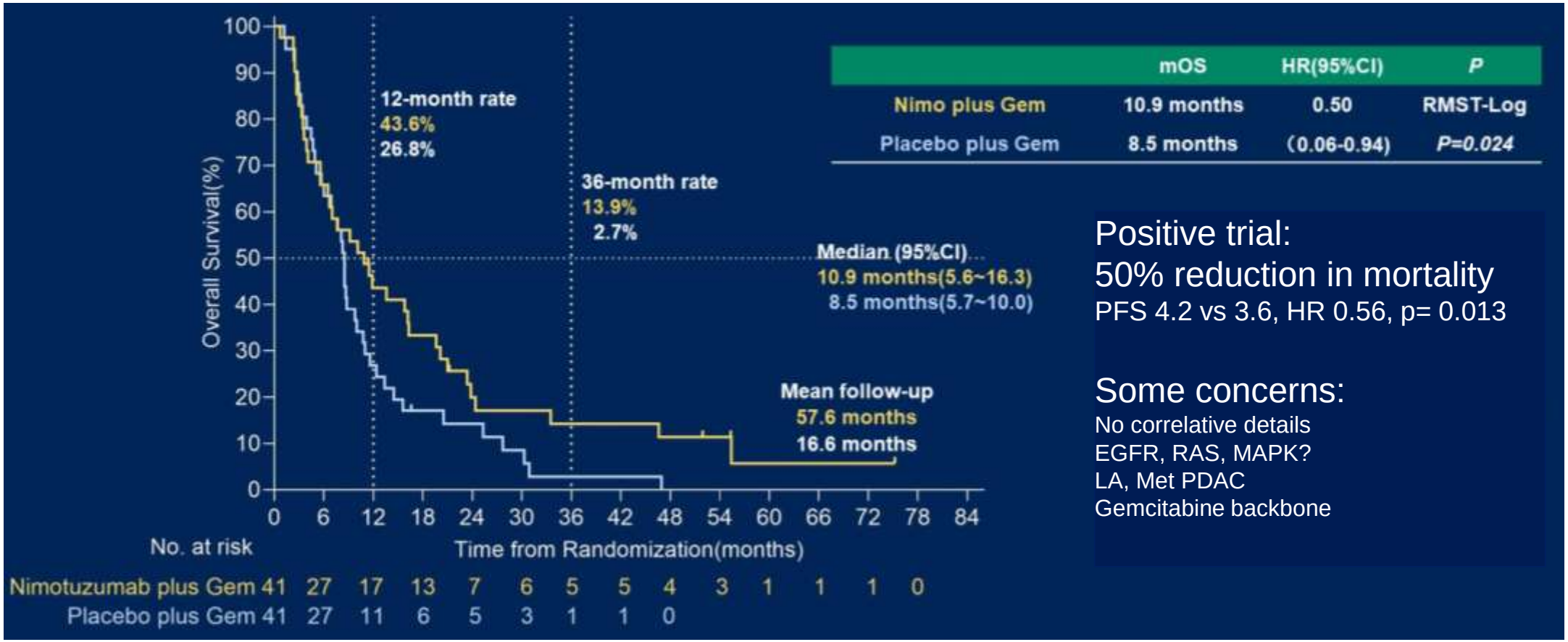
Can respond well to chemotherapy

Testing methodology key
DNA, RNA

Schram, A. ASCO, 2021
Varghese, A. JNCI, 2021
Singhi, AD. Gastroenterology, 2019
Schram, A. Cancer Disc, 2022
Schram, A. ASCO, 2022

Phase III NOTABLE Trial in *KRAS*^{WT} PDAC (N= 82)

Gemcitabine +/- Nimotuzumab (Anti-EGFR mAntibody)



	mOS	HR(95%CI)	P
Nimo plus Gem	10.9 months	0.50	RMST-Log
Placebo plus Gem	8.5 months	(0.06-0.94)	P=0.024

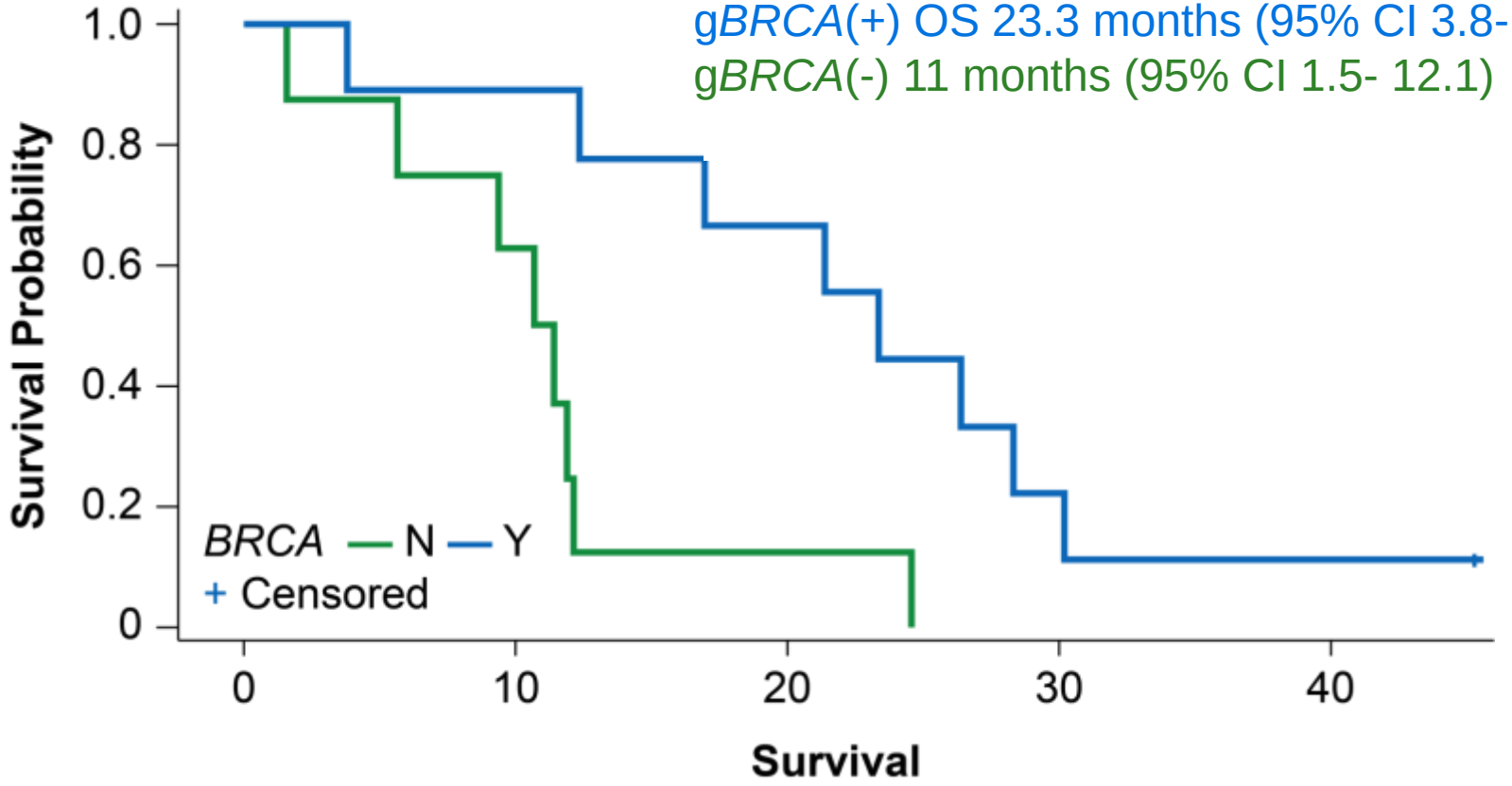
Positive trial:
50% reduction in mortality
PFS 4.2 vs 3.6, HR 0.56, p= 0.013

Some concerns:
No correlative details
EGFR, RAS, MAPK?
LA, Met PDAC
Gemcitabine backbone

Qin, S. Abstract LBA 4011, ASCO, 2022
Qin, S. J Clin Oncol, 2023

DNA Damage Repair Directed Therapy

Prospective Platinum-Based Therapy g*BRCA* vs Wild-Type
g*BRCA1/2, PALB2*: Improved Outcome

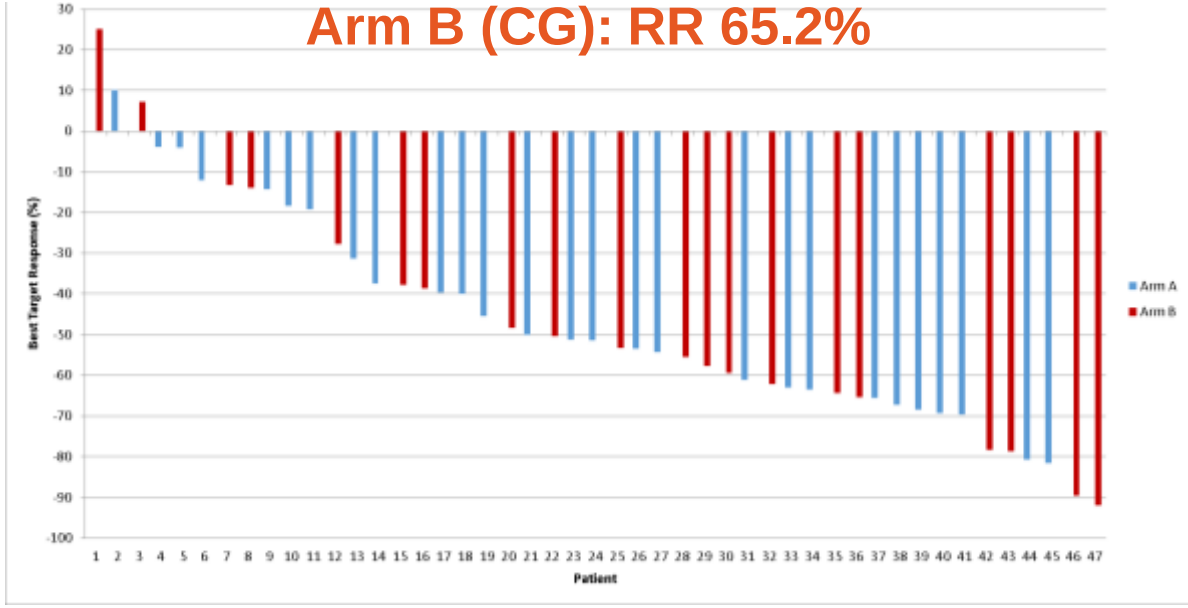


g*BRCA*(+) OS 23.3 months (95% CI 3.8- 30.2)
g*BRCA*(-) 11 months (95% CI 1.5- 12.1)

O'Reilly EM…Kelsen, DP. Cancer, 2018

Cisplatin/Gem +/- Veliparib g*BRCA1/2, PALB2*:
Randomized Phase II Advanced PDAC

Arm A (CGV): RR 74.1%
Arm B (CG): RR 65.2%



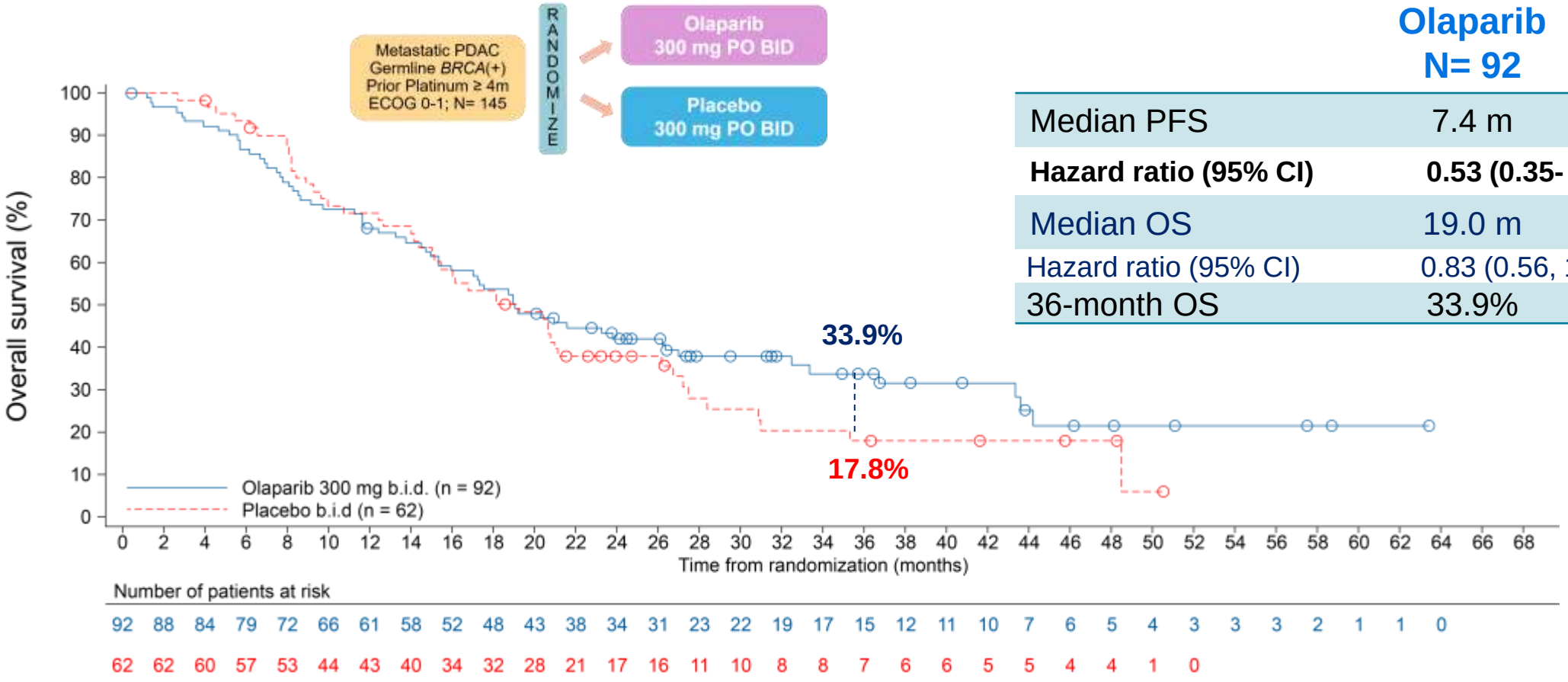
	Cis, Gem, V N= 27	Cis, Gem N= 23
Response Rate	74%	65%
Overall Survival	15.5 m	16.4 m
Combined Arms (N= 50)		
2-Year OS	31% (CI 17.8%- 44.4%)	
3-Year OS	18% (CI:8.1%- 30.7%)	
Platinum → PARPi	23 m (CI: 6.5- 53.9)	

- Defines a standard regimen *BRCA1/2, PALB2*

O'Reilly, EM…Kelsen, DP. J Clin Oncol, 2020

POLO g*BRCA*: Maintenance Olaparib vs Placebo

PFS Positive; No Overall Survival Benefit



	Olaparib N= 92	Placebo N= 62
Median PFS	7.4 m	3.8 m
Hazard ratio (95% CI)	**0.53 (0.35- 0.82); p= 0.004**	
Median OS	19.0 m	19.2 m
Hazard ratio (95% CI)	0.83 (0.56, 1.22); p= 0.3487	
36-month OS	33.9%	17.8%

Golan, T. New Eng J Med, 2019
Kindler, H. J Clin Oncol, 2022

POLAR: Pembrolizumab OLAparib

Phase II Maintenance 1L/2L Trial – Building on POLO, PARPVAX

Metastatic PDAC/Acinar

Platinum Response 1st/2nd Line

ECOG 0-1

A. Core HRD (N= 32)

Germline/Somatic *BRCA1/2, PALB2;* SD/PR > 4m platinum

B. Non-Core HR (N= 15)

15 genes: *ATM, BAP1, BARD1, BLM, BRIP1, CHEK2, FAM175A, FANCA, FANCC, NBN, RAD50, RAD51, RAD51C, RTEL1, MUYTH*; SD/PR > 4m platinum

C. CR/PR Platinum (N= 15)

Genotype (-); PR/CR > 6m platinum

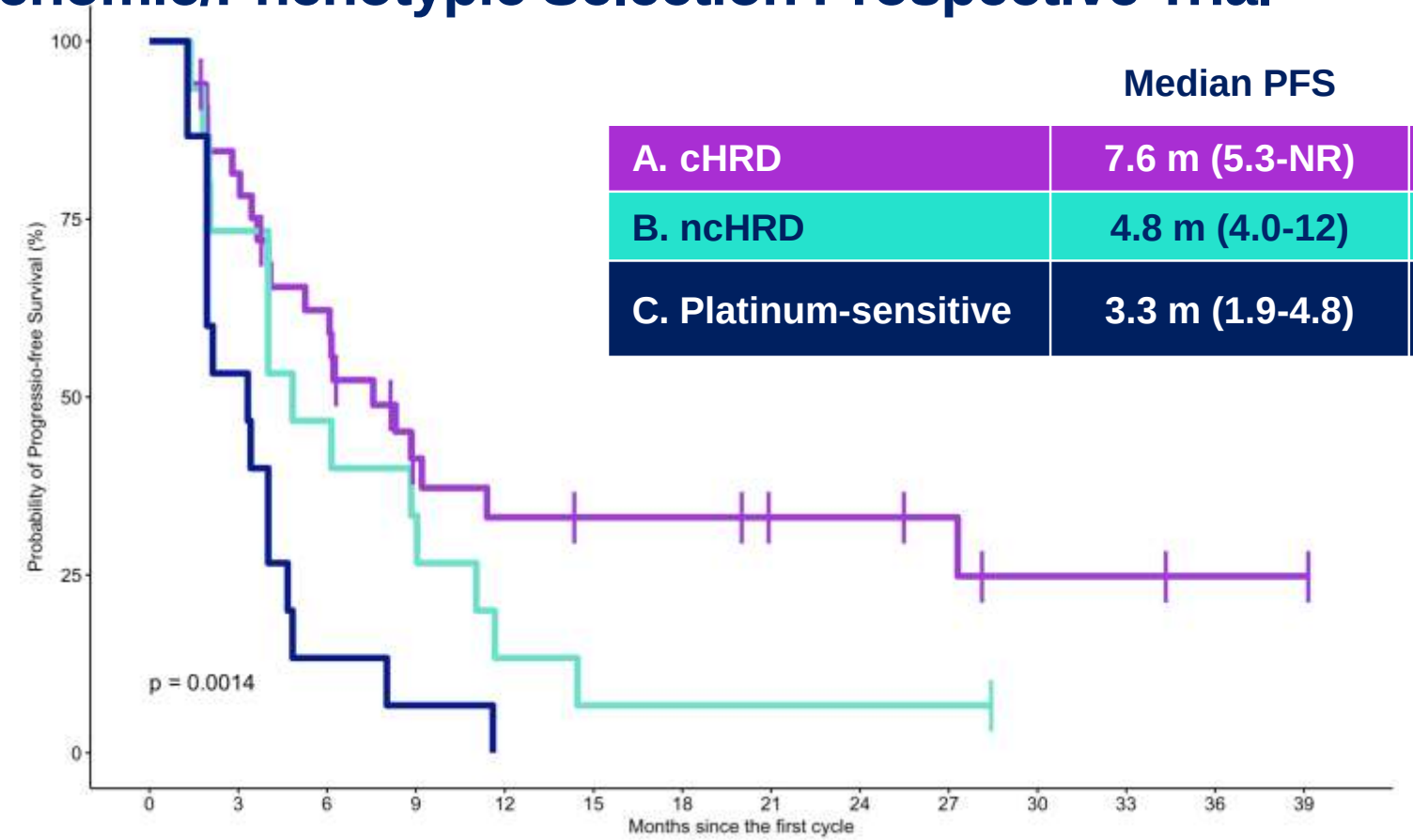
Olaparib + Pembrolizumab

Cohort A: Co-Primary ORR or PFS @6M; Simon-2 stage
Cohort B, C: Exploratory single arm design ORR

Golan, T. NEJM 2019, Kindler, HJ JCO, 2022
Reiss, K…Vonderheide, R. Lancet, 2022
Park, W. O'Reilly, EM NCT04666740
Park, W.. O'Connor, C….O'Reilly, EM. ESMO, 2024

POLAR: Maintenance Olaparib/Pembrolizumab (N= 63)

Genomic/Phenotypic Selection Prospective Trial



	Median PFS	ORR*	DCR	Median OS
A. cHRD	7.6 m (5.3-NR)	35%	80%	Not Reached
B. ncHRD	4.8 m (4.0-12)	8%	75%	18 m (13-)
C. Platinum-sensitive	3.3 m (1.9-4.8)	14%	50%	10 m (8.5, 24)

*Measurable

- Ability to stratify patients based on core vs non-core vs platinum-sensitive

Park, W. O'Connor, C…..O'Reilly, EM. ESMO, 2024

Acinar Cancer: *BRCA*/HR-Related Cancer

High Frequency of Homologous Repair Deficiency

MSK cohort N= 49 (MSK-IMPACT 2015- 2022)

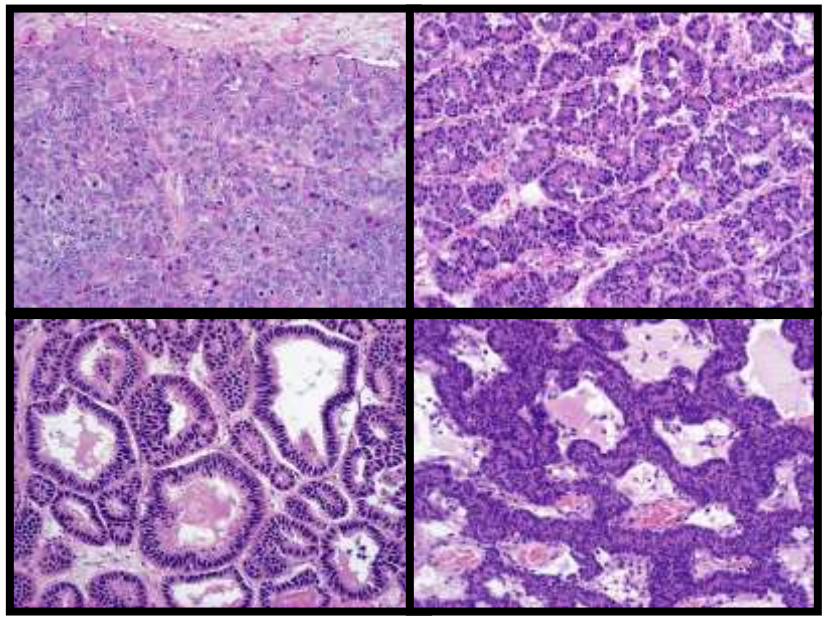
Pathogenic variant HR/DDR gene in 37%

BRCA1 (N= 1); *BRCA2* (N= 12); *PALB2* (N= 2); *ATM* (N= 2); *CHEK2* (N= 1)

WGS acinar with DDR gene variant: 100% HRD

Higher level of neoantigens relative to PDAC

Classify *BRCA*-related cancer?



Mandelker, D…. Reis-Filho, J. J Clin Oncol, 2023

Selected Ongoing Trials in HRD/ *BRCA/PALB2* in PDAC

APOLLO EA2192:
Adjuvant Olaparib vs Placebo

- Resected; completed all standard therapy
- N= 152; Primary endpoint: RFS (22 → 44 months; 90% power, HR 0.5)

SWOG/Alliance S2001:
Maintenance Olaparib +/- Pembrolizumab

- *BRCA1/2, PALB2* germline/somatic > 4 m platinum therapy
- N= 88; Primary endpoint: PFS (HR 0.6; 7→ 11.7 m)

PLATINUM A022106
Randomized phase II/III 2L: Cisplatin/gemcitabine/nab-paclitaxel vs Gemcitabine/nab-paclitaxel

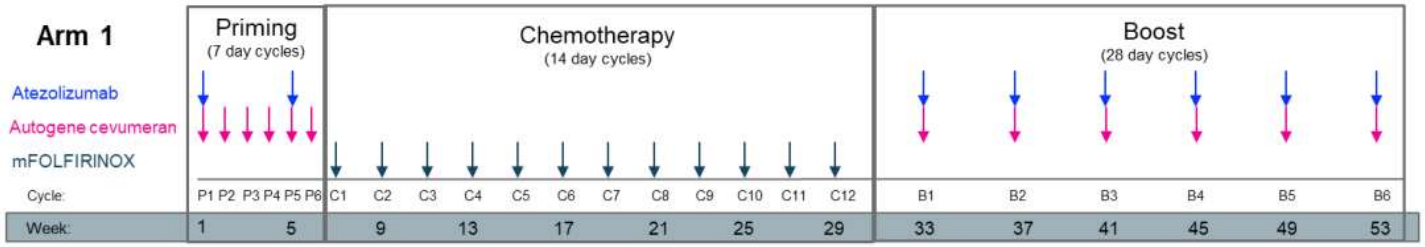
- g/s*BRCA1/2, PALB2*
- N= 100; Primary endpoint ORR (phase II); OS (phase III)

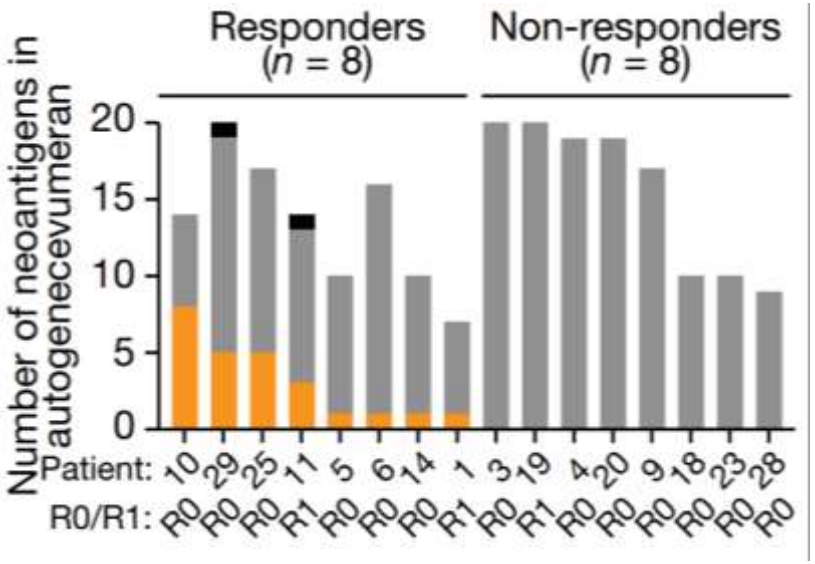
NCT04858334 Reiss Binder (PI)
NCT04548752 Chung, Pishvaiain (PI)
NCT06115499 Ko, Tsang (PI)

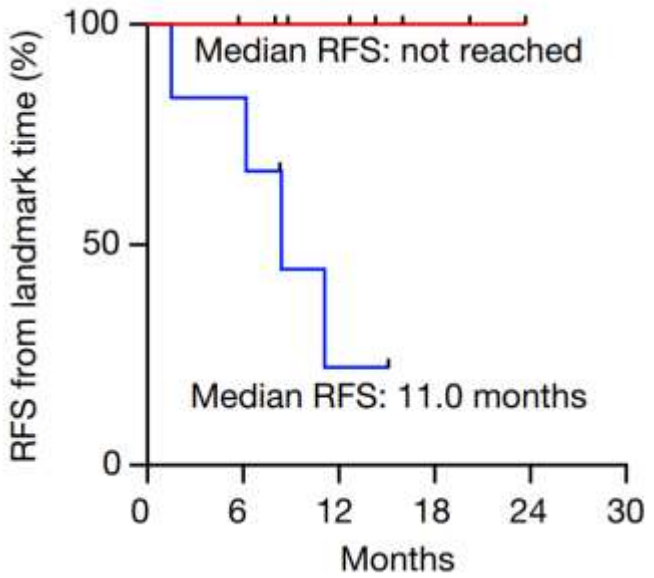
Immunotherapy – Emerging Promise

Phase I Adjuvant Autogene Cevumaren, Atezolizumab, mFFX
Resected Pancreas Cancer: Immune Response Correlates with RFS

N= 16 treated (28 screened)
50% immune responders







Rojas, L..Balachandran, V. Nature, 2023

Randomized Phase II Resected PDAC

mFOLFIRINOX +/- mRNA Neoantigen Vaccine (Autogene cevumaren) + anti-PDL1

Resected PDAC
2-part screening

ECOG 0-1
Ca 19-9 ≤ 180 U/ml

1:1 Randomization

N= 260

Arm A: Autogene Cevumaren weekly x6 + Atezolizumab (priming) → mFOLFIRINOX x12 → Autogene Cevumaren/Atezolizumab x6 (boost)

Arm B: mFOLFIRINOX x12 (SOC)

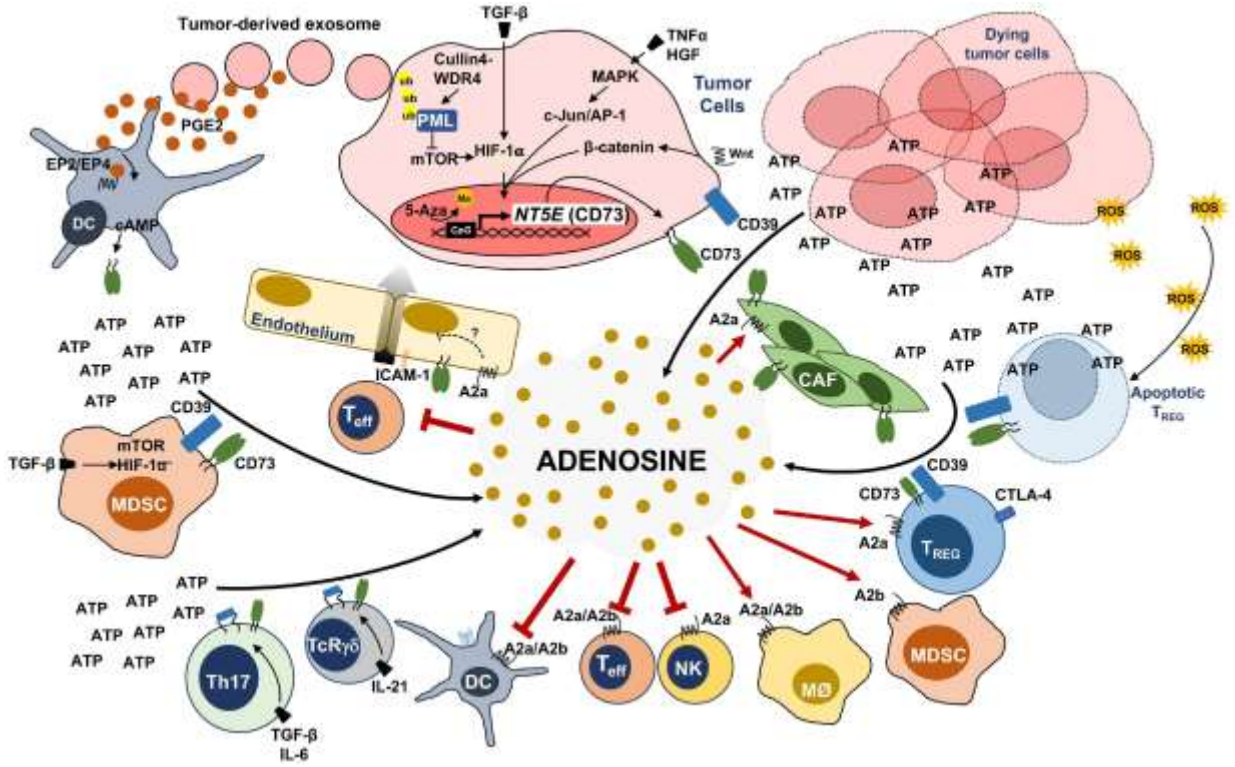
Primary endpoint: Disease-free survival (investigator)
Secondary: DFS @12, 24, 26 m; OS, OS @3, 5 years; Safety
Exploratory: QoL; QLQ-C30, EORTC PAN-26, PRO-CTCAE; PK; Immunogenicity
Stratification: R0 vs R1, N0 vs N1

G044479
NCT05968326

Elevated CD73 Expression and Adenosine Mediated Immune Suppression

PDAC tumor immune microenvironment:

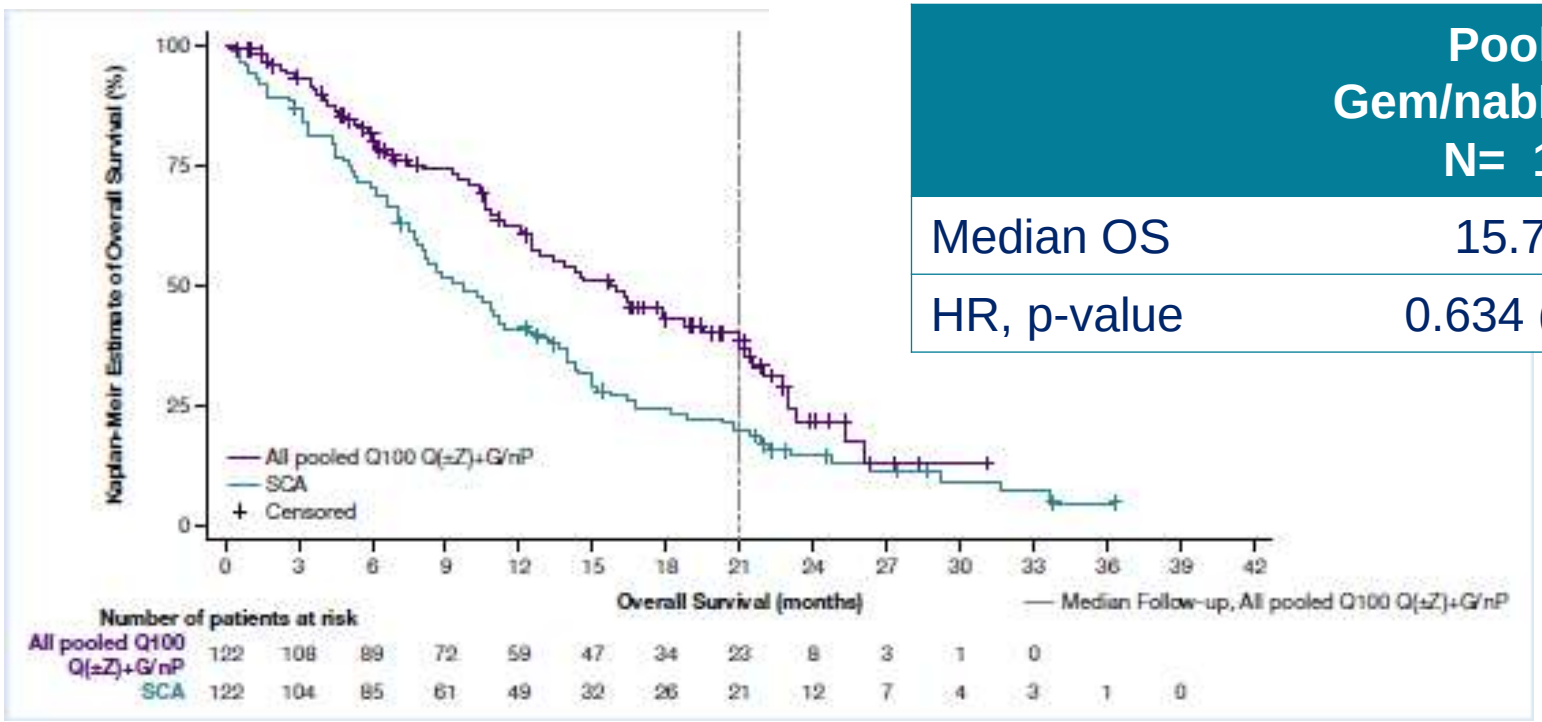
- High levels CD73
- CD73 expression associated with *KRAS* mutant phenotype
- High CD73 expression associated with worse outcome



Tahkola, K. Virchows Arch, 2020
Zhao, J. Pancreatology, 2021
Silva-Viches, C. Front Immunol, 2018
Allard, D. Immunol Letters, 2019

ARC-8: Phase I/IB: Gem/Nab-P + Quemliclustat (anti-CD73)

Promising Early Signal – Phase III Ongoing



	Pooled Gem/nabP+Q+/-Z N= 122	SOC Control N= 122
Median OS	15.7 m	9.8 m
HR, p-value	0.634 (0.471, 0.854); p= 0.0030	

PRISM 1: Randomized phase III gemcitabine/nab-paclitaxel +/- quemliclustat/placebo (N= 610; 2: 1)
Opened late 2024

Wainberg, Z...O'Reilly, EM. Gastrointestinal Cancers Symposium, 2024
NCT06608927

Other Biomarker Based Approaches in PDAC

Claudin 18.2: Promising Target in PDAC

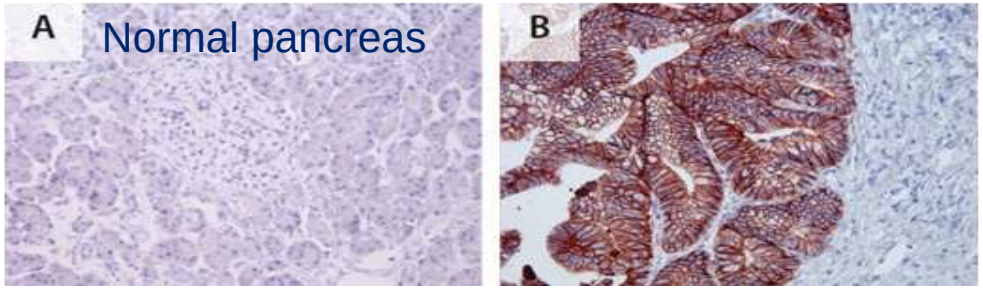
Rand. Phase II Gemcitabine/nab-Paclitaxel +/- Zolbetuximab

Metastatic PDAC
CLDN 18.2(+)
ECOG 0-1
N= 357

2: 1

Gemcitabine/nab-Paclitaxel + Zolbetuximab (N= 238)
1000 mg/m^2 day 1 (load), 600 mg/m^2 day 1, 15

Gemcitabine/nab-Paclitaxel (N= 119)



Zolbetuximab: mAb IgG1 CLDN 18.2: ADCC, CDC
Primary endpoint: OS
10.5 m → 15.0; 80% power, 2-sided 0.05, HR 0.776

ACCRUED: Awaiting outcome

Eligibility: CLDN 18.2 mod/strong ≥ 75% tumor cells (IHC)

Park, W..Kunieda, F. Trials in Progress 4186, ASCO, 2022. NCT03816163

IBI389: Bispecific Ab Targets CD3, Claudin 18.2 PDAC

IBI389

Anti-CD3/ anti-CLDN 18.2, IgG-like

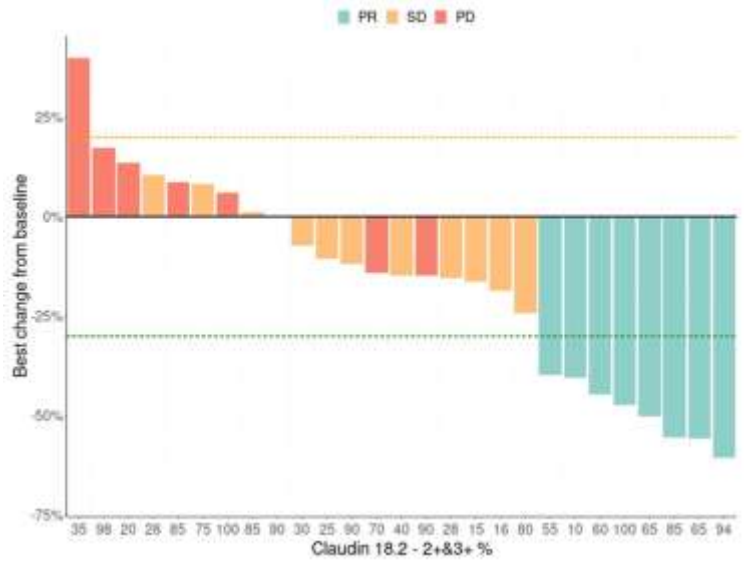
Cross-links CD3+ T cells, CLDN 18.2+ cells, CTL's

Phase I advanced PDAC N= 72

- Recommended phase II (RP2D) 600 ug/kg
- IHC 2/3+ ≥ 10% (N= 27) → RR 29.6%
- IHC 2/3+ ≥ 40% (N= 18) → RR 38.9%
- 1 CRS/tocilizumab
- Ongoing trials: IBI-389 + sintilimab (anti-PD1)

Other agents/mechanisms targeting CLDN:

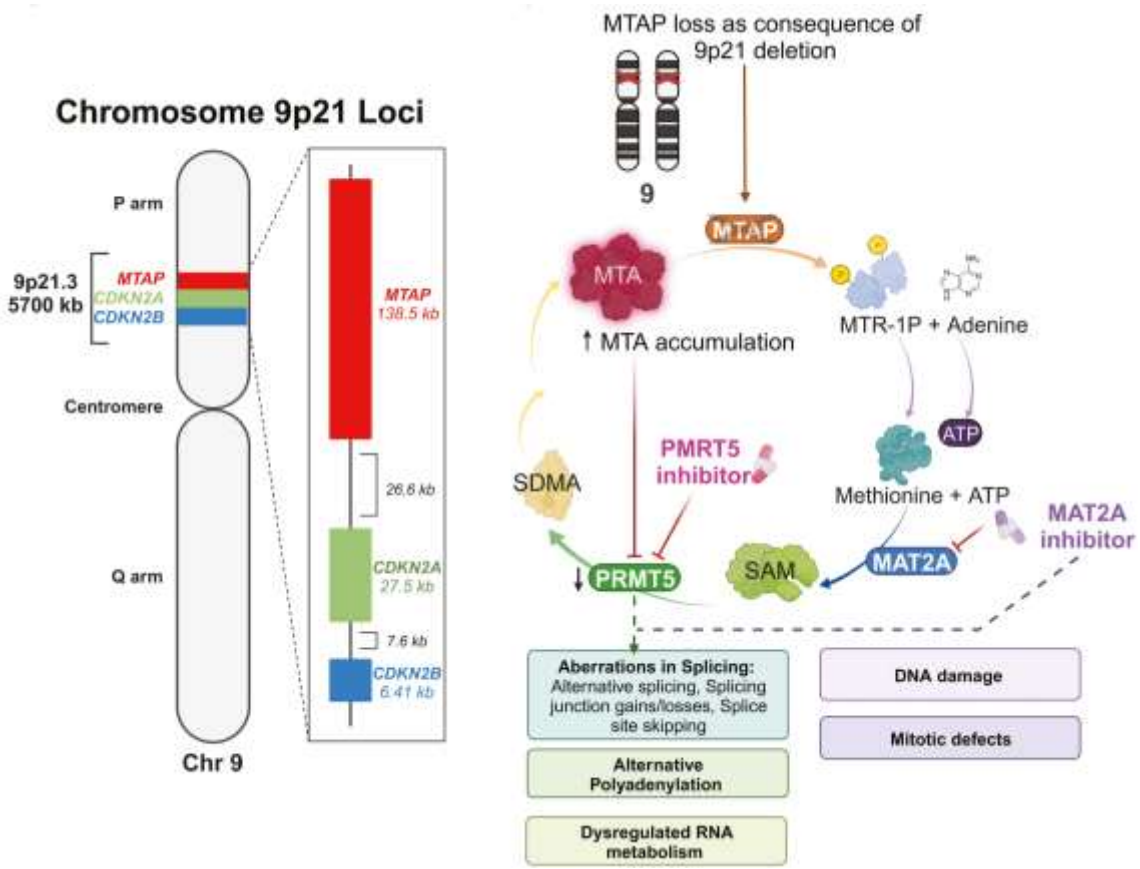
IBI343 ADC, IBI345 CAR T



Hao, J, et al. ASCO 2024, Abst 4011
Xiangjun Yu, et al. ASCO 2024, Abst 3037
NCT05164458
NCT05458219

Synthetic Lethality: New Approach – PRMT5, MTA Inhibition

- Methylthioadenosine phosphorylase (*MTAP*)
- *MTAP* deletion/loss ~15% multiple solid tumors; 8% GI cancers; PDAC 15- 25%
- *MTAP* adjacent, often co-deleted *CDKN2A* (9p21)
- *MTAP, CDKN2A* associated with resistance to IO therapies ('cold' TME)
- *MTAP*-loss novel biomarker for agents inhibiting MAT2A and PRMT5
- *MTAP* associated with resistance to ICB



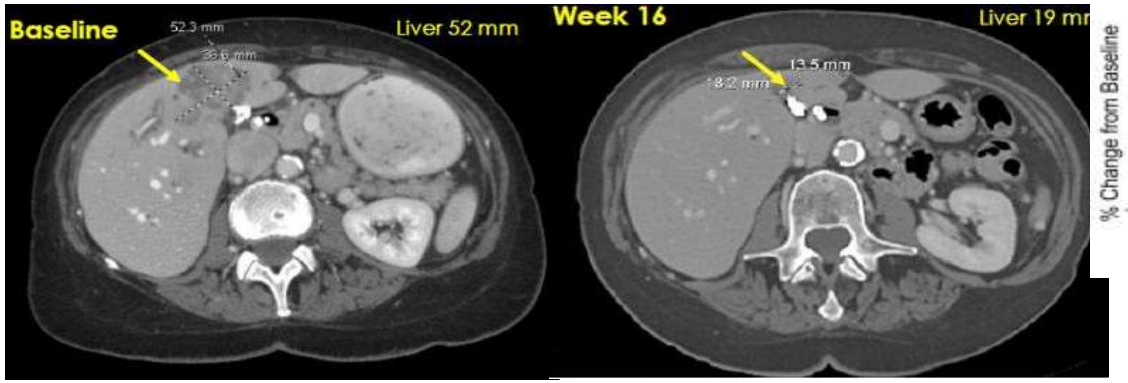
Ngoi, NYL…Rodon Ahnet. Oncologist, 2024
Stopa, N. Cell Reports, 2016
Rodon, J. AACR-EORTC-NCI, 2023

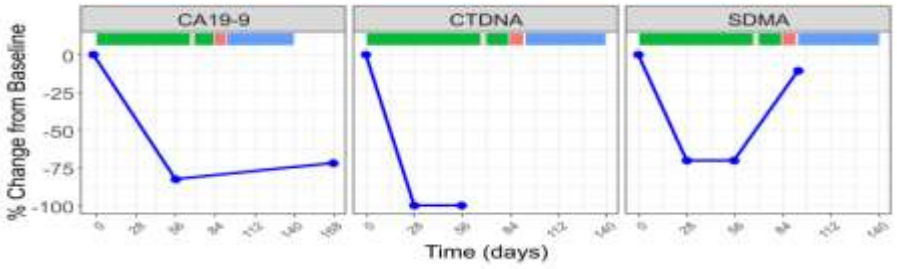
MTAP-Deleted Solid Tumors: Phase I AMG 193 (5 PR's)

RP2D 1200 mg PO

Gallbladder

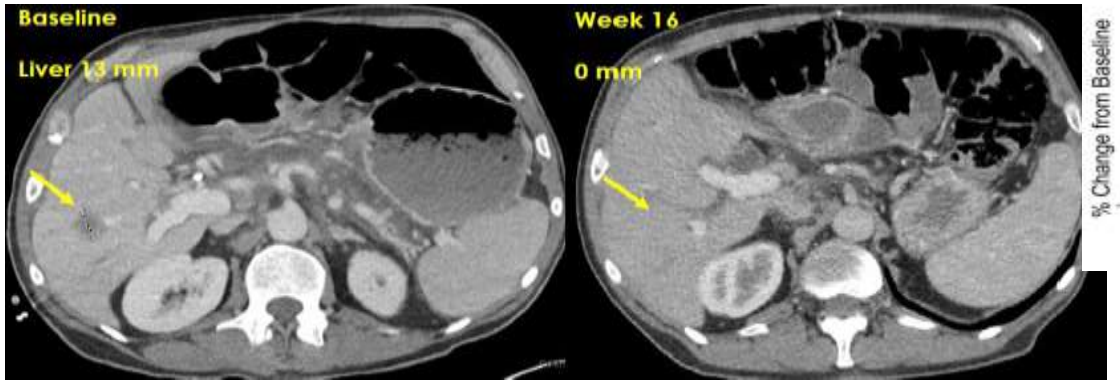
76 y/o Female
4 prior lines
- *TP53m*
- *ERBB2* amplification
- *CDKN2A/2B* loss
  MTAP-loss

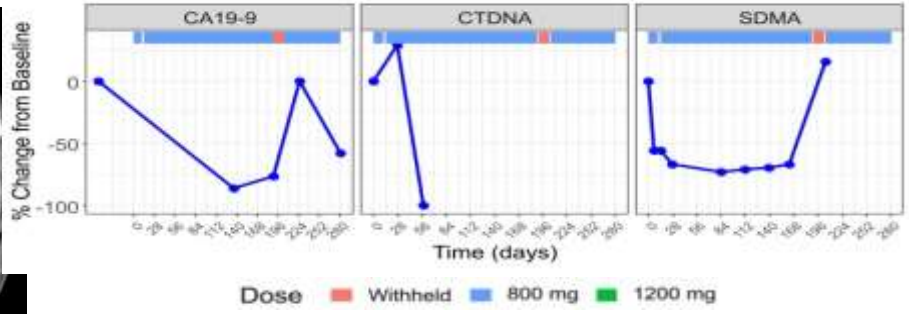




Pancreas Cancer

65 y/o male
2 prior lines
- *TP53m*
- *CDKN2A/2B*-loss, *MTAP*-loss
- *KRAS*





- ESMO 2024 PDAC sub-cohort N= 23: 5 PR's (2 confirmed); 4 SD
- Multiple PRMT5, MAT2A agents/combinations in development

Rodon, J. EORTC-NCI-AACR (ENA), 2023
Sacher, A. Abstract 604O, ESMO, 2024

Antibody Drug Conjugates in Development in PDAC

NCT	Therapeutic	Mechanism/Target	N	Study Design
NCT0591535	Enfortumab vedotin	NECTIN-4, MMAE	28	Phase II, single arm, two-stage; ORR
NCT04843709	MRG004A	Tissue factor/CD142	181	Phase I, II
NCT06131840	SGN-CEACAM5C	CEA, Topo-1	410	Phase I, II
NCT06219941	AZD0901	Claudin 18.2, MMAE	390	Phase II, multiple arms

Many other targets

EGFR, mesothelin, Trop 2, HER3, MUC1, Gypican-1 (GPC-1), CD71, DR5, C-MET, EphA2

DESTINY PanTumor02 Biliary, PDAC

Trastuzumab deruxtecan (T-DXd: HER2(+) IHC 1-3 (mostly

Response rate 4%; mFS 3.2 m

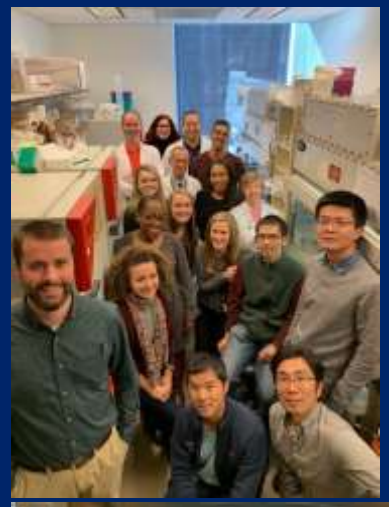
Oh, Do You, et al. ASCO 2024 Abst 4090
NCT0448309
Martin, M. Critical Reviews Oncology/Hematology, 2024

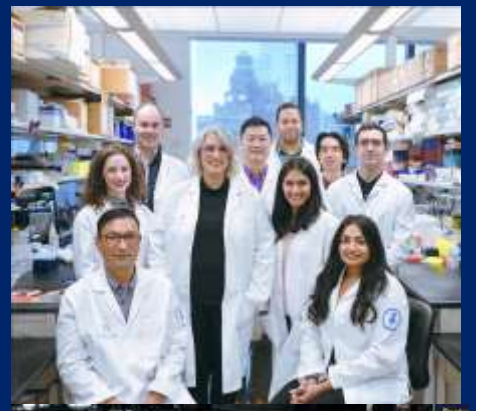
Conclusions: Best Oncologic Therapies for PDAC 2025

Standard Therapy - Selection	• ECOG 0-1: (m)FOLFIRINOX, Gemcitabine/nab-P, NALIRIFOX • Transcriptomic classifiers to inform first-line choice?
Biomarker Selected Subsets	• Germline, somatic testing; DNA, RNA (fusions) • Increasing subsets biomarker directed opportunities *g/sBRCA1/2, PALB2*, *KRAS* wild-type, MSI-H, *KRAS* G12C, fusions
Emerging Approaches (beyond RAS)	• Claudin: Antibody, bispecifics, ADC's • *MTAP* – multiple agents – single/combination • Novel immune therapies, anti-CD73, vaccines

John Hopkins GI Conference

Thank You!





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