
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16 OF
THE SECURITIES EXCHANGE ACT OF 1934**

For the month of December 2020

Commission file number: 001-35223

BioLineRx Ltd.

(Translation of registrant's name into English)

**2 HaMa'ayan Street
Modi'in 7177871, Israel**
(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F ☒ **Form 40-F** ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulations S-T Rule 101(b)(7): _____

On December 16, 2020, management of the registrant will hold a KOL webinar at 8:00 a.m. ET to discuss the results of the COMBAT/KEYNOTE-202 clinical study. A copy of the presentation being used in connection with this webinar is furnished herewith as [Exhibit 1](#) to this Report on Form 6-K.

In addition, on December 16, 2020 the registrant issued the press release which is filed as Exhibit 2 to this Report on Form 6-K.

The first, second, and third paragraphs, the table containing the data summary and the paragraph following immediately thereafter in the press release attached to this Form 6-K are hereby incorporated by reference into all effective registration statements filed by the registrant under the Securities Act of 1933.

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

BioLineRx Ltd.

By: /s/ Philip A. Serlin
Philip A. Serlin
Chief Executive Officer

Dated: December 16, 2020

Transforming science into medicine



KOL Webinar to Discuss Final Results
from **COMBAT/KEYNOTE-202** Phase 2a
Study in Metastatic Pancreatic Cancer

December 16, 2020

BIOLINERX

Forward-Looking Statements

Various statements in this presentation concerning BioLineRx's future expectations constitute "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include words such as "may," "expects," "anticipates," "believes," and "intends," and describe opinions about future events. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance or achievements of BioLineRx to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Factors that could cause BioLineRx's actual results to differ materially from those expressed or implied in such forward-looking statements include, but are not limited to: the initiation, timing, progress and results of BioLineRx's preclinical studies, clinical trials and other therapeutic candidate development efforts; BioLineRx's ability to advance its therapeutic candidates into clinical trials or to successfully complete its preclinical studies or clinical trials; BioLineRx's receipt of regulatory approvals for its therapeutic candidates, and the timing of other regulatory filings and approvals; the clinical development, commercialization and market acceptance of BioLineRx's therapeutic candidates; BioLineRx's ability to establish and maintain corporate collaborations; BioLineRx's ability to integrate new therapeutic candidates and new personnel; the interpretation of the properties and characteristics of BioLineRx's therapeutic candidates and of the results obtained with its therapeutic candidates in preclinical studies or clinical trials; the implementation of BioLineRx's business model and strategic plans for its business and therapeutic candidates; the scope of protection BioLineRx is able to establish and maintain for intellectual property rights covering its therapeutic candidates and its ability to operate its business without infringing the intellectual property rights of others; estimates of BioLineRx's expenses, future revenues, capital requirements and its needs for additional financing; risks related to changes in healthcare laws, rules and regulations in the United States or elsewhere; competitive companies, technologies and BioLineRx's industry; risks related to the coronavirus outbreak; and statements as to the impact of the political and security situation in Israel on BioLineRx's business. These and other factors are more fully discussed in the "Risk Factors" section of BioLineRx's most recent annual report on Form 20-F filed with the Securities and Exchange Commission on March 12, 2020. In addition, any forward-looking statements represent BioLineRx's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. BioLineRx does not assume any obligation to update any forward-looking statements unless required by law.

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Featured KOLs

Gulam Manji, M.D., Ph.D. is an Assistant Professor of Medicine and Director of Medical Oncology & Translational Research for The Pancreas Center at Columbia University Medical Center. Dr. Manji completed his PhD from the University of Wisconsin-Madison and Internal Medicine Residency at Albany Medical College. He then completed his fellowship in Hematology/Oncology at New York-Presbyterian/Columbia, where he remained as faculty within the Division of Hematology and Oncology.


Talia Golan, M.D. is a highly qualified medical oncologist and researcher in the field of pancreatic cancer. She specializes in gastrointestinal malignancies and serves as a director of the Phase I clinical trials unit at Sheba's Pancreatic Cancer Center. She has earned a world-renowned reputation for her studies in the field of pancreatic cancer. Her current research trials are being carried out in conjunction with two of the world's largest biopharmaceutical companies, AstraZeneca and MSD (Merck).

Manuel Hidalgo, M.D., Ph.D., is currently the Chief of the Division of Hematology and Medical Oncology at Weill Cornell Medicine/New York-Presbyterian Hospital. Dr. Hidalgo received his M.D. from the University of Navarra in Pamplona, Spain in 1992, and Ph.D. from University Autonoma of Madrid in 1997. He trained in medicine and medical oncology at Hospital "12 de Octubre" in Madrid and at the University of Texas Health Science Center in San Antonio, Texas. He also completed a fellowship program in anticancer drug development at the Institute of Drug Development in San Antonio.

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Agenda

- I. **Philip Serlin**, Chief Executive Officer, BioLineRx – Introductory comments
- II. **Gulam Abbas Manji, MD/PhD**
- III. **Dr. Golan Talia Golan, MD**
- IV. **Manuel Hidalgo, M.D., Ph.D.**
- V. **Q&A**
- VI. **Philip Serlin – Closing remarks**



Targeting CXCR4 with combination chemotherapy and immunotherapy in Pancreas Ductal Adenocarcinoma

Gulam Abbas Manji, MD/PhD

Assistant Professor, Division of Hematology and Oncology
Director of Pancreas Medical Oncology and Translational Medicine
Columbia University Irving Medical Center

December 16, 2020



COLUMBIA UNIVERSITY
HERBERT IRVING COMPREHENSIVE
CANCER CENTER



Disclosures

Research Funding

- Genentech/Roche
- Merck
- BioLineRx
- Regeneron
- Plexxikon

Advisory Role

- Genentech/Roche
- BioLineRx
- Ipsen

Immune Checkpoint Blockade (ICB) and Pancreas Cancer

PDL1 and TIL

Retrospective – Resected PDA (N=51)

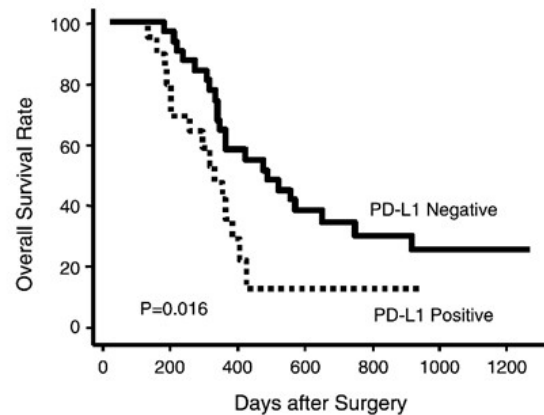
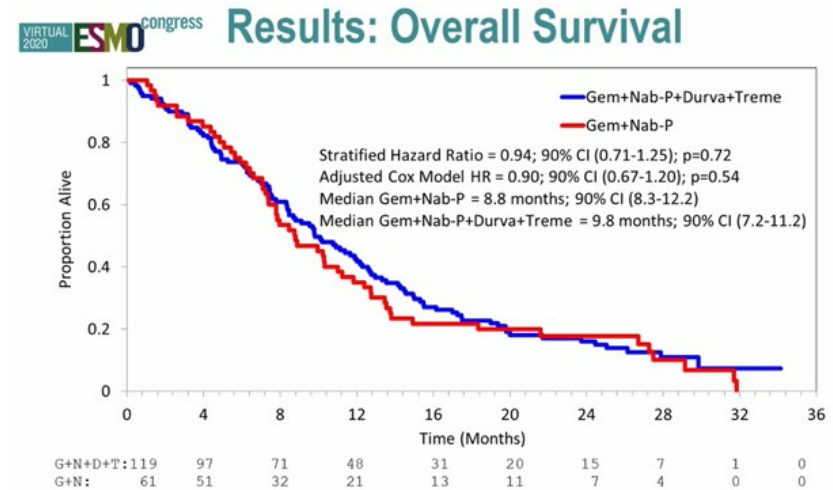


Table 2. Inverse correlation between tumor PD-L1 status and TILs

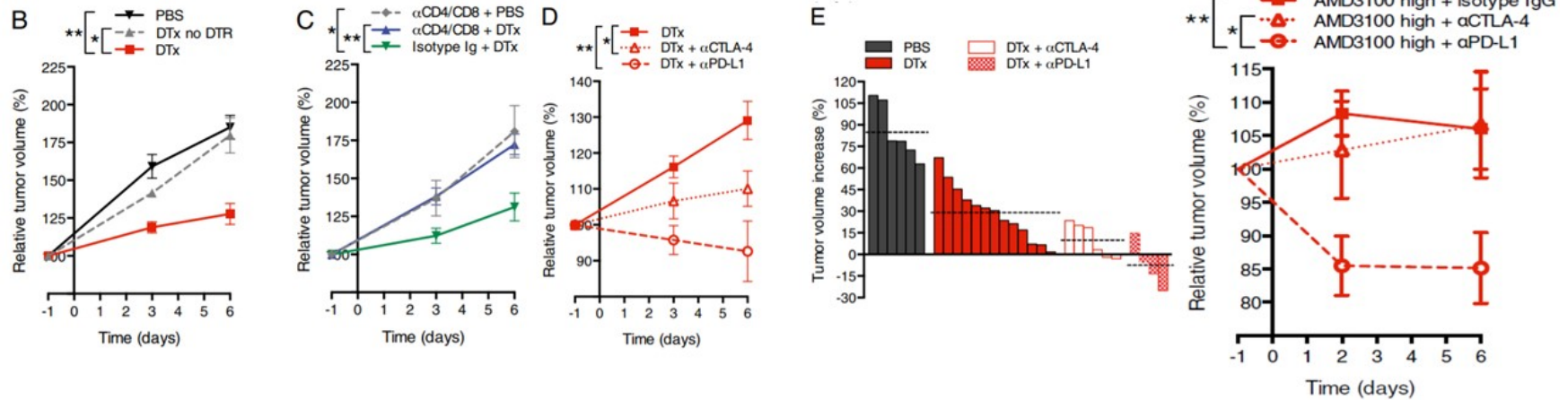
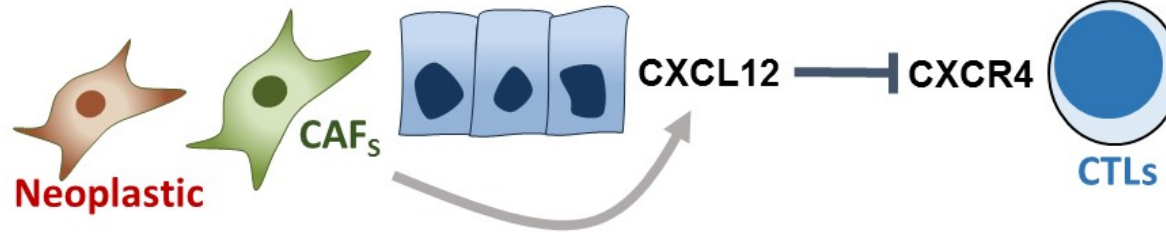
PD-L1	CD4		CD8	
	Positive	Negative	Positive	Negative
Positive	9	11	5	15
Negative	24	7	25	6

Nomi, T. CCR. 2007; 13:251-7



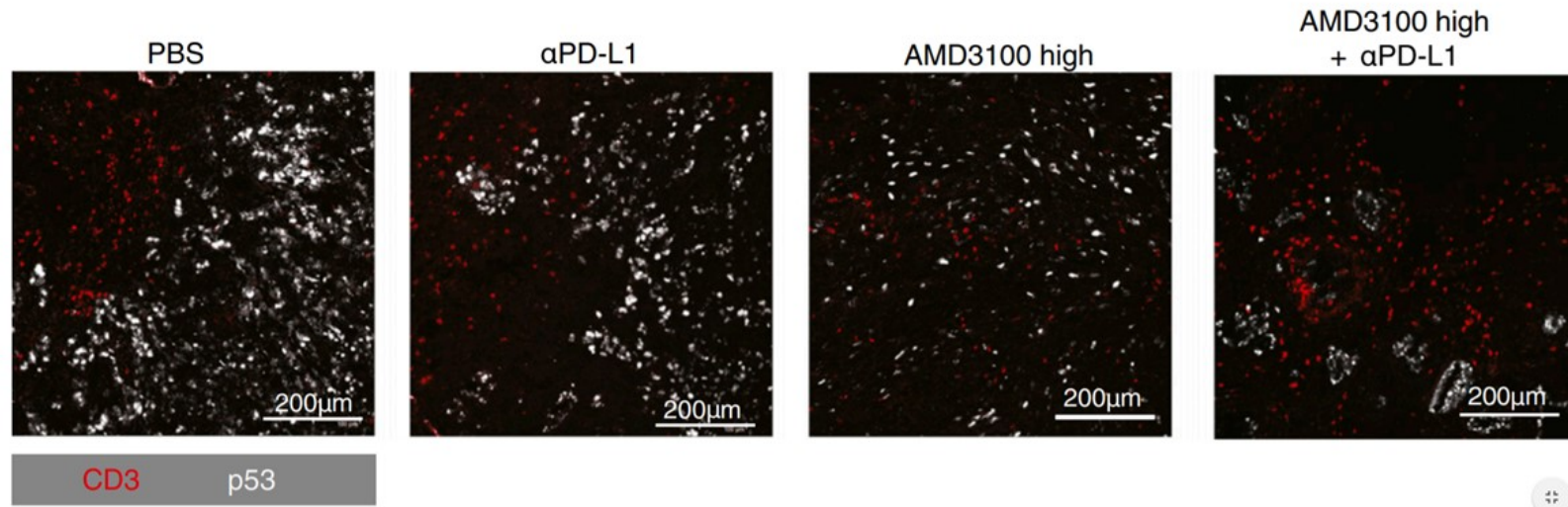
Dr. Daniel Renouf, BC Cancer, University of British Columbia, Vancouver, Canada
 Renouf D, Knox J, Kavan P, Jonker D, Welch S, Couture F, Lemay F, Tehfe M, Harb M, Aucoin N, Ko Y, Tang P, Ramjessingh R, Meyers B, Kim C, Schaeffer D, Lorne J, Graham B, Tu D, O'Callaghan C
 Canadian Cancer Trials Group Groupe canadien des essais sur le cancer 40 YEARS

CXCR4 inhibition Leads to Tumor Stabilization - Preclinical



Feig C, et al. PNAS. 2013. 110:20212-7

CXCR4 inhibition (CXCR4i) Leads to T-cell Infiltration



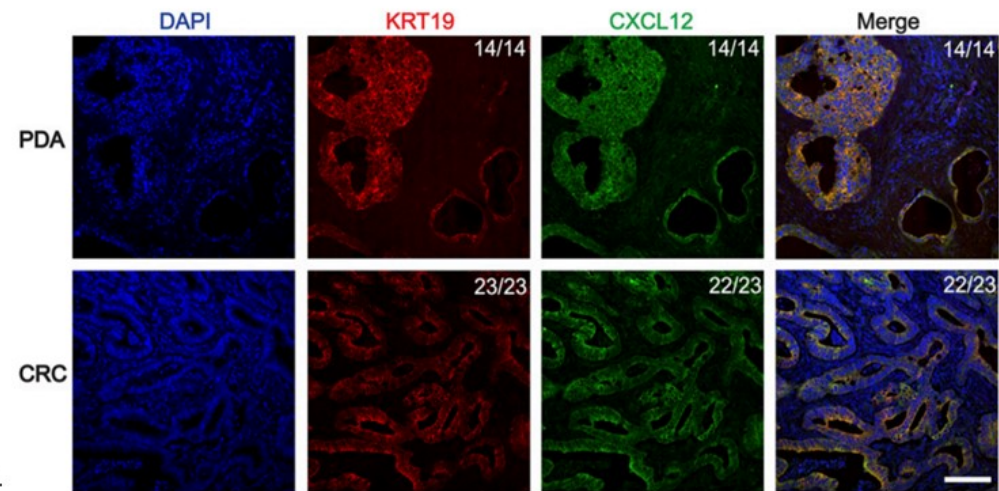
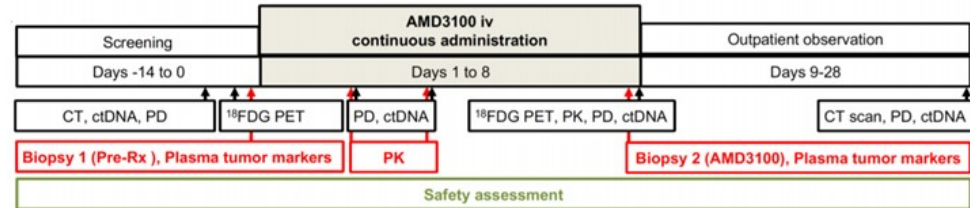
Feig C, et al. PNAS. 2013. 110:20212-7

CXCL12 Colocalizes with Tumor Cells in Pancreatic Cancer

NCT03277209 –

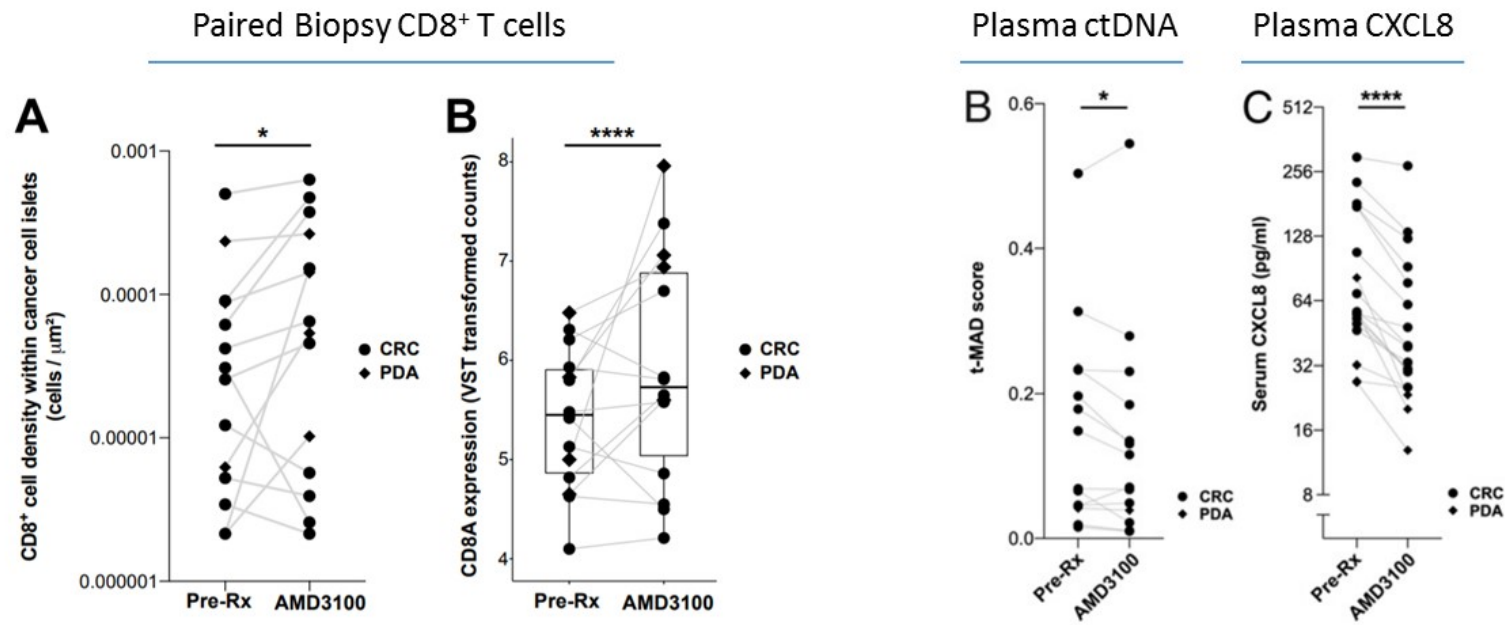
Dose escalation of continuous IV administration of **AMD3100**

Treatment resistant MSS CRC and PDAC



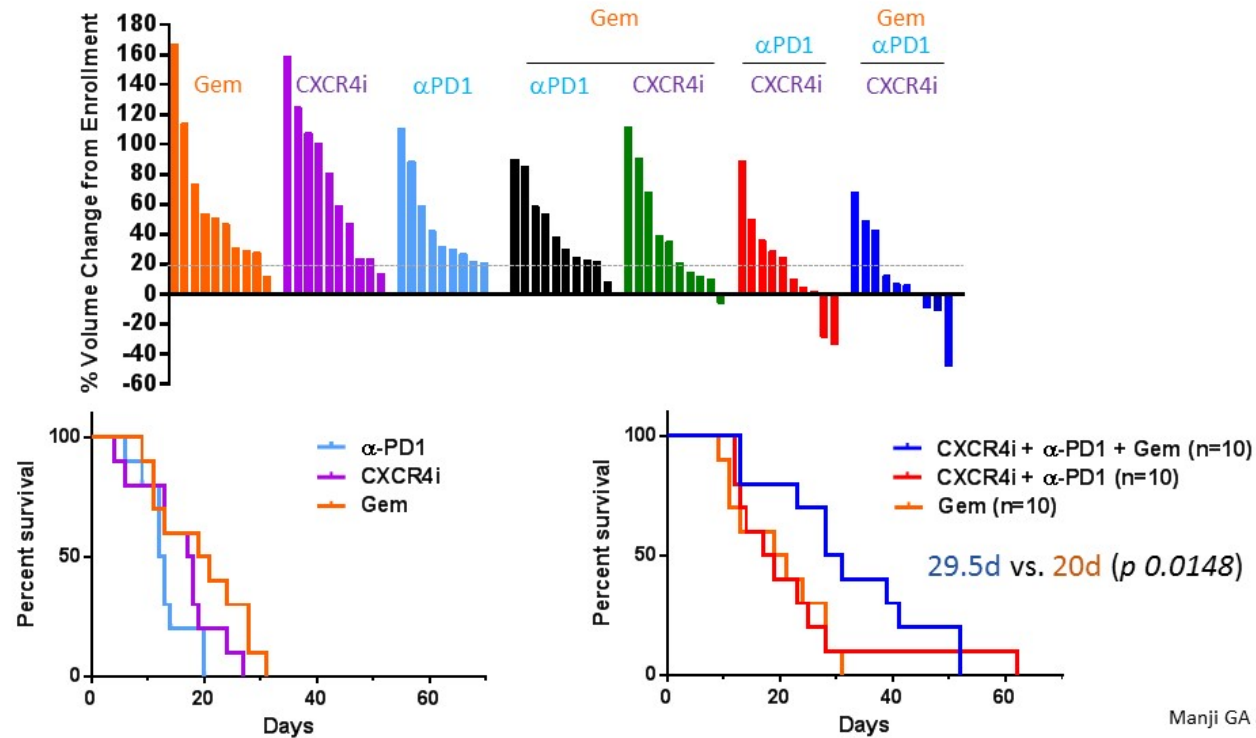
Biasci D, et al. Proc Natl Acad Sci U S A. 2020 Nov 17;117(46):28960-28970.

CXCR4i Increases CD8 T-cell Infiltration



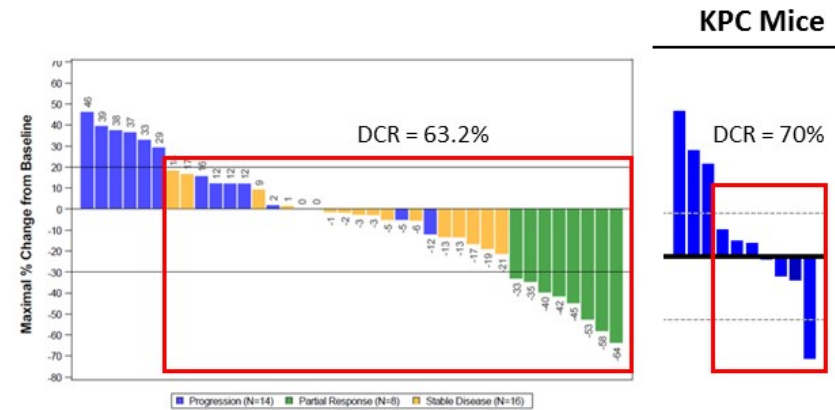
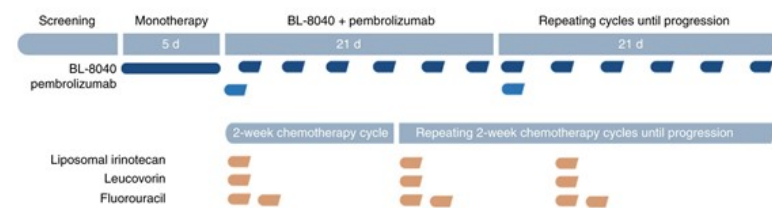
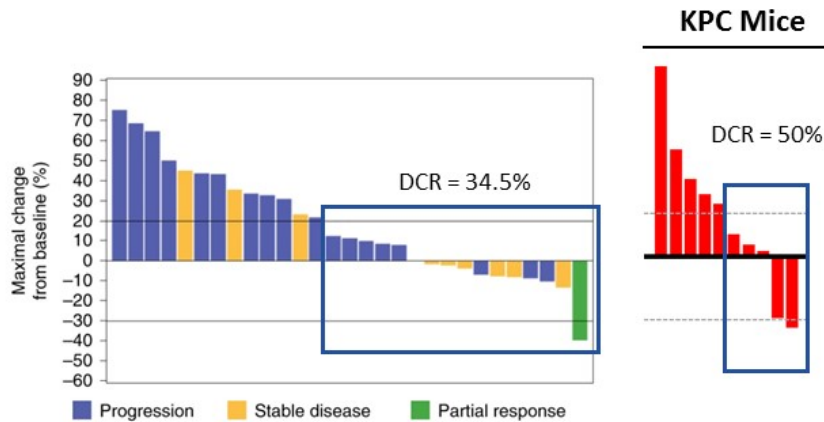
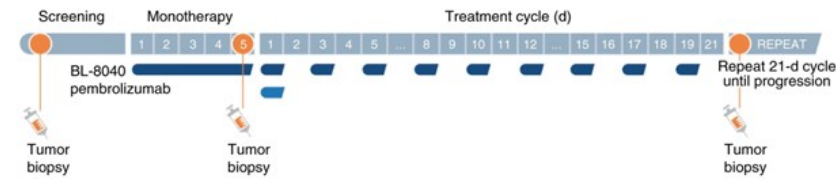
Biasci D, et al. Proc Natl Acad Sci U S A. 2020 Nov 17;117(46):28960-28970.

CXCR4i, ICB, & Gemcitabine Improve Survival - Preclinical



Manji GA and K Olive, Unpublished

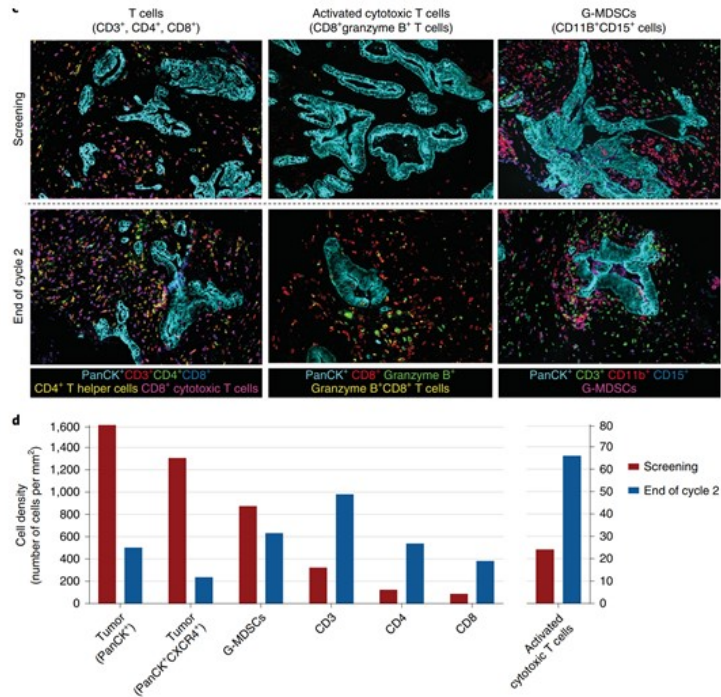
Chemotherapy Enhances Efficacy of CXCR4i and ICB



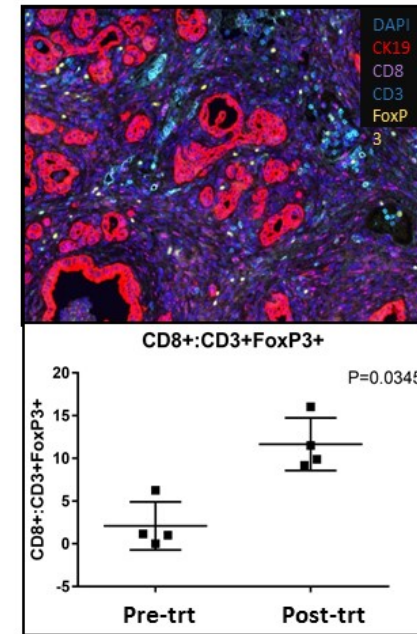
Manji GA and K Olive, Unpublished
Bockorny B et al. *Nature Medicine*. 26, pages878–885(2020)

CXCR4i Improves Tumor Immune Profile

Human – COMBAT Study-dual combination

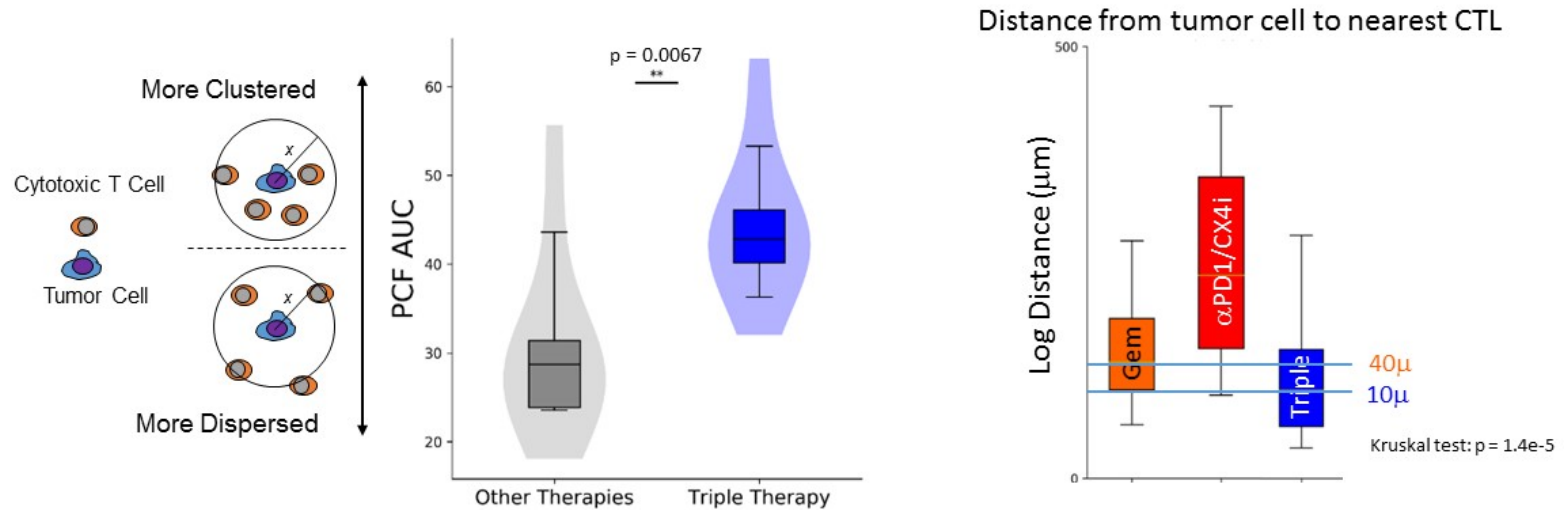


KPC Mice Triple Therapy



Manji GA and K Olive, Unpublished
Bockorny B et al. *Nature Medicine*. 26, pages878–885(2020)

Chemotherapy, CXCR4i and ICB results in T cell clustering



Manji GA and Rabadan R, Unpublished

Summary

- Inhibition of CXCR4 in combination with chemotherapy and ICB in KPC mice –
 - Increases CD 8+ T cell/FoxP3+
 - Improves proximity of CD8+ T cells to neoplastic cells
 - Improves survival
- Inhibition of CXCR4 in patients with pancreas cancer –
 - Increases CD8+ T cells (AM3100 and Motixafortide with ICB)
 - Decreases MDSCs (Motixafortide with ICB)
 - Encouraging efficacy in preliminary study with combination with 5-FU, liposomal irinotecan and ICB

Updates in PDAC

Talia Golan, MD

Medical Director, Phase I Program
& Sheba Pancreatic Cancer Program
Sheba Medical Center, Israel



December 2020

Disclosures

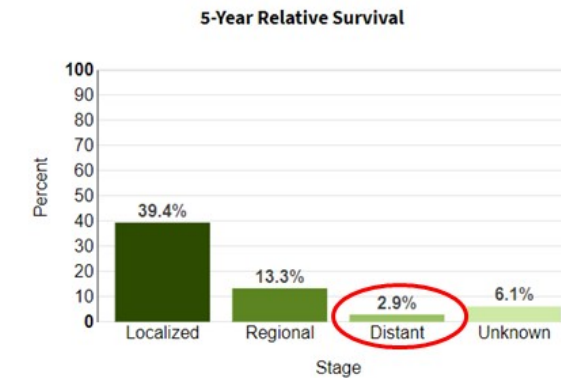
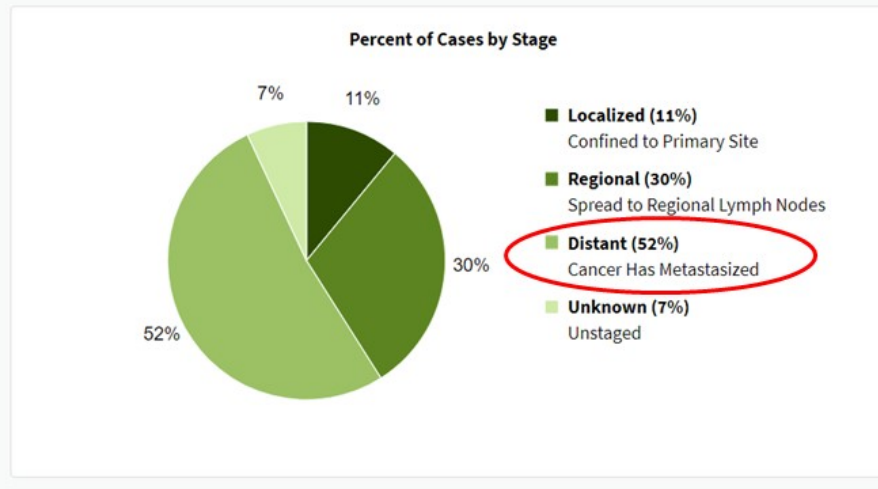
Receipt of grants/research supports: Astra Zeneca and MSD Merck

Receipt of honoraria or consultation fees: Abbvie, BioLineRx, MSD Merck, Bayer and Teva

Agenda

- The current state of pancreatic cancer treatment
- Benchmarks for PDAC
- Immunotherapy in pancreatic cancer
- Summary

Percent of Cases & 5-Year Relative Survival by Stage at Diagnosis: Pancreatic Cancer

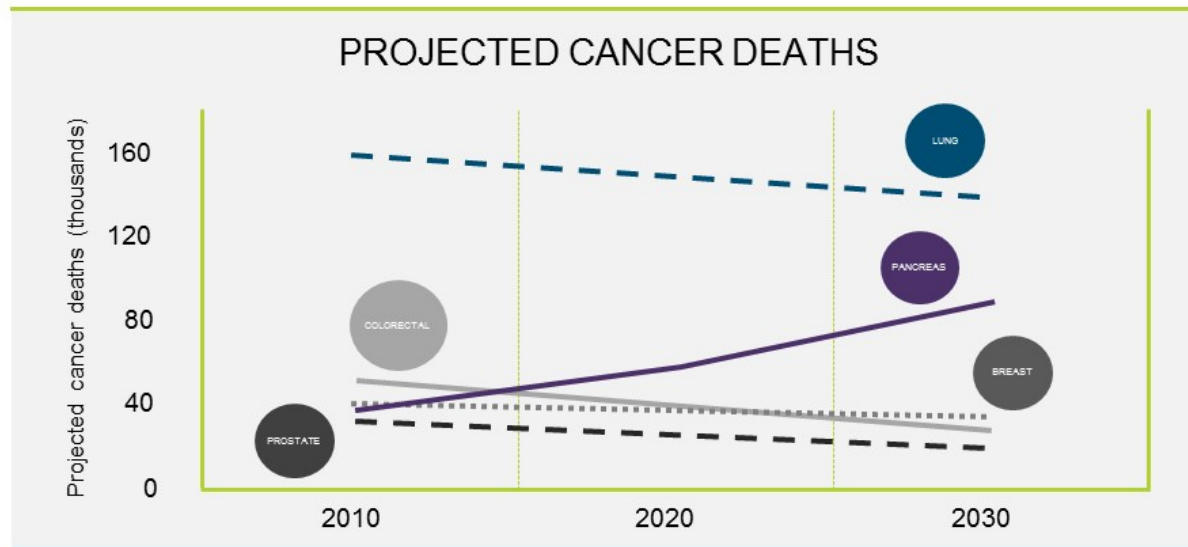


The majority of PDAC patients are diagnosed with metastatic disease

The current state of pancreatic cancer treatment

Within this decade, pancreatic cancer will become the 2nd leading cause of cancer death in the United States

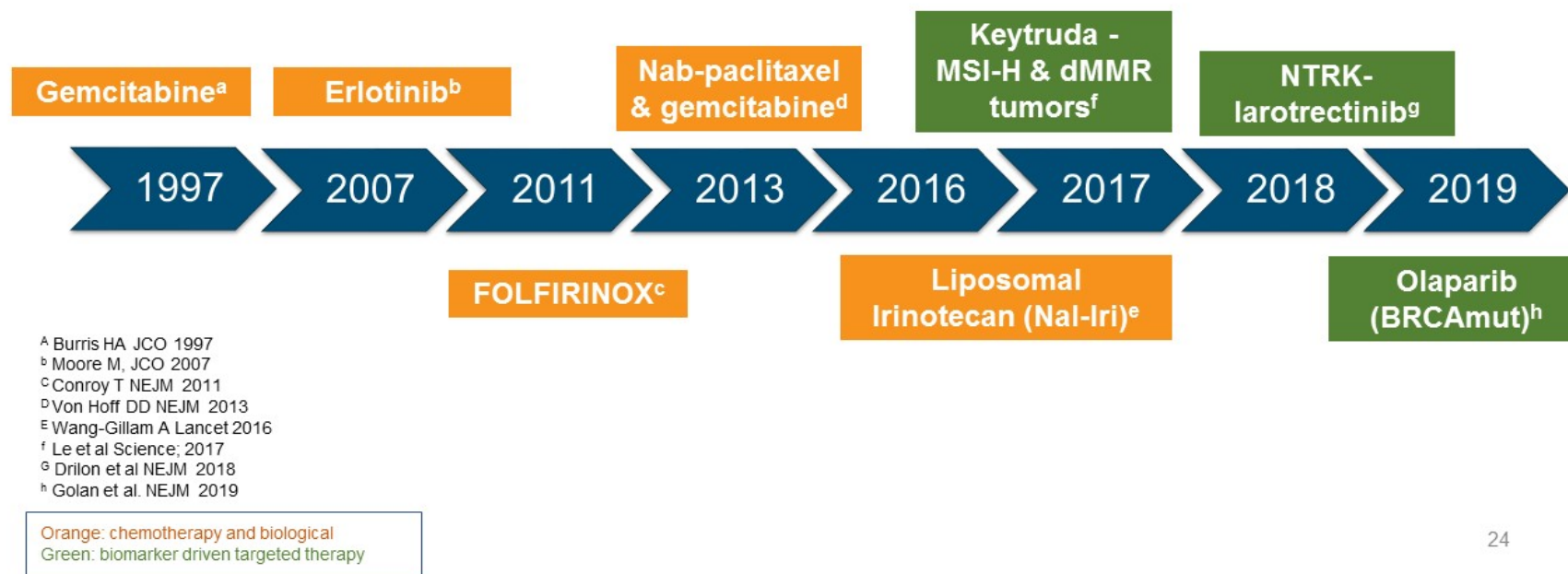
- Pancreatic cancer is the only one of the top 5 cancer killers for which deaths are **projected to increase**



Multiple Drugs and Targets Have Failed in Clinical Trials PDAC: Dec 2015 – Dec 2020

Drug	Target/Mechanism	Phase	Number of Patients
Evofofosfamide	Alkylator (Hypoxia)	III	694
Ruxolitinib	JAK1/2	III	Early termination
Necuparanib	Heparan mimetic	I/II	128
Masitinib	TKI (Kit, Lyn, Fyn)	III	353
Vandetanib	TKI (VEGFR2, RET, EGFR)	II	142
Algenpantucel-L	Vaccine	III	722
CRS-207 + GVAX	Vaccine	I/II	240
Tarextumab	Notch2/3	II	177
Demcizumab	DLL4	II	204
⁹⁰ Y-Clivatuzumab Tetraxetan	MUC1	III	334
Apatorsen	HSP27	II	132
Z-360	CCK2	II	167
Simtuzumab	LOX-2	II	240 (159)
MM-141	IGF-1R/ErbB-3	II	88
Ibrutinib	BTK	III	424
Napabucasin	STAT3	III	>1,100
Pegilodecakin (AM0010)	pegylated IL-10	III	567
PEGPH20	Hyaluron	III	500
Cabiralizumab	CSFR-1	I/II	160

Therapeutics in advanced PDAC Over 2 Decades

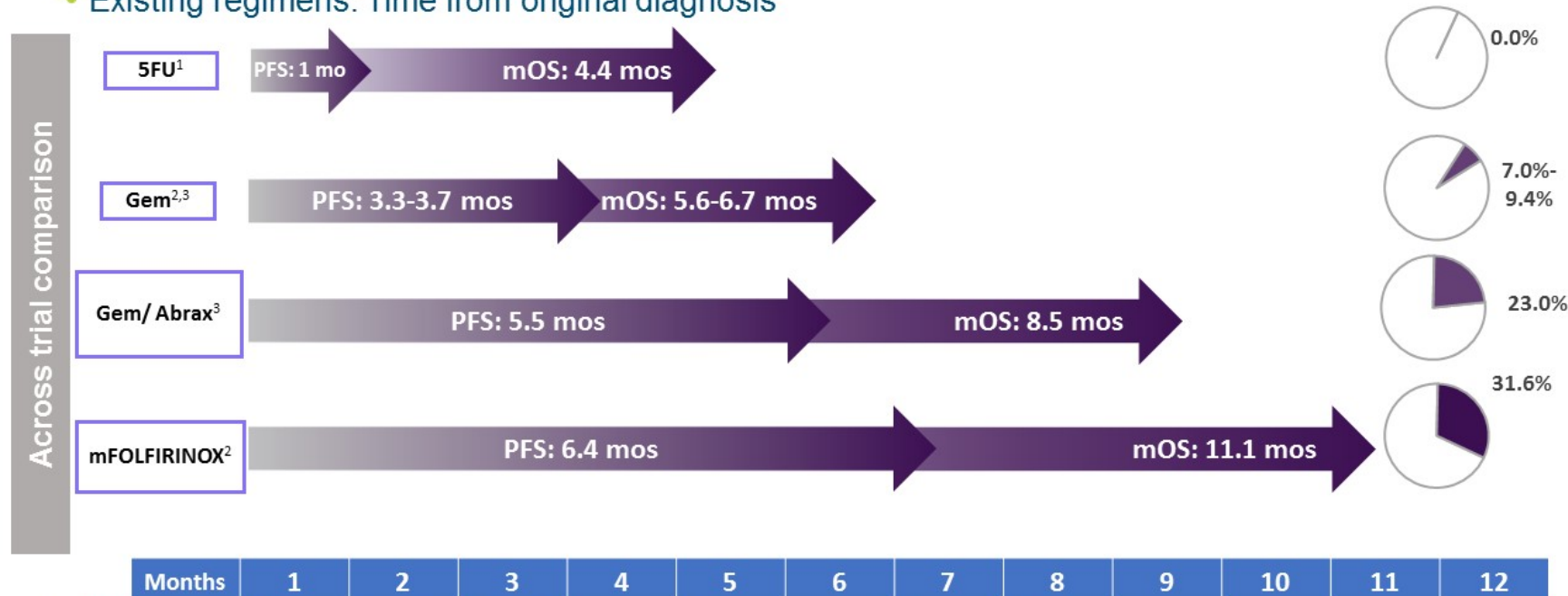


Benchmark for Pancreatic Cancer

There is a significant unmet need to prolong disease control and survival as part of first-line treatment for patients with pancreatic cancer

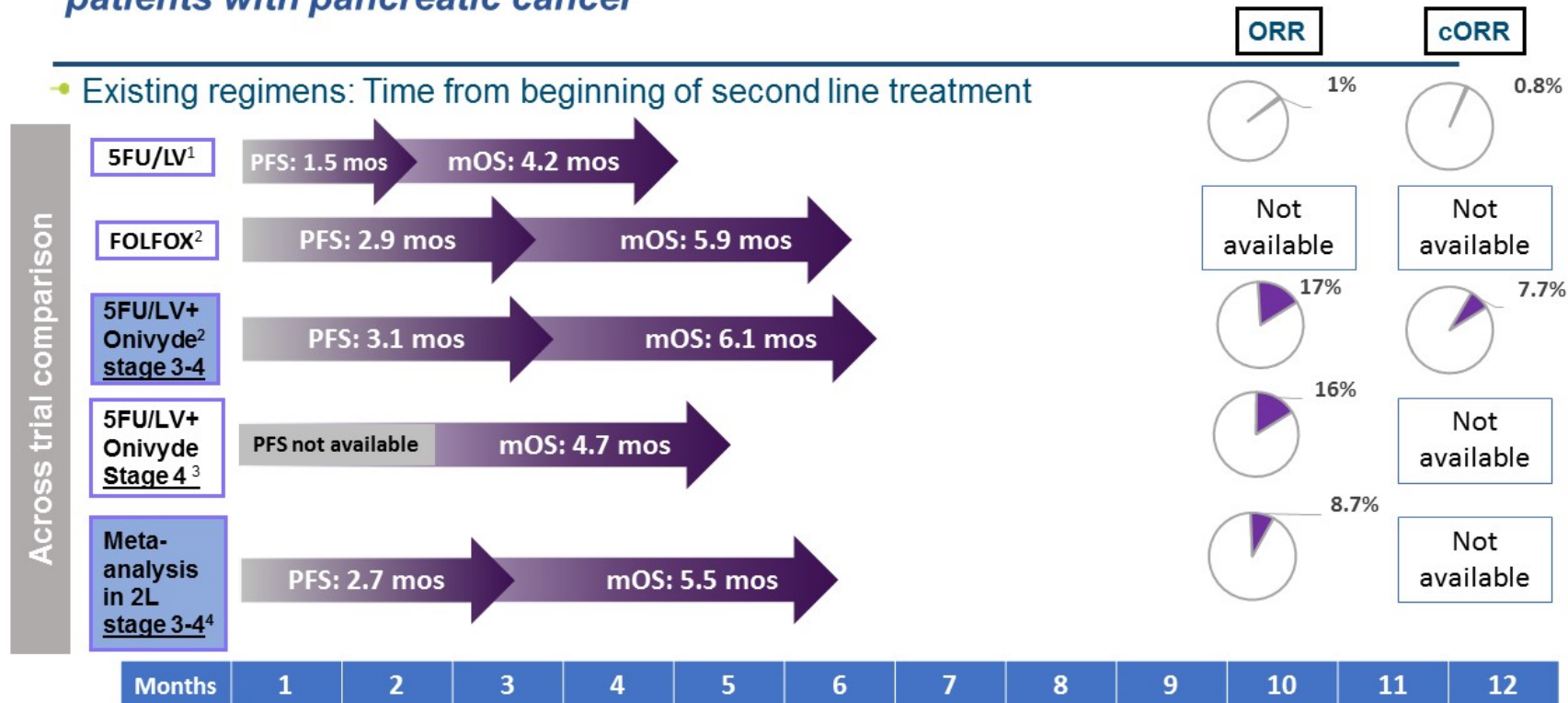
ORR

- Existing regimens: Time from original diagnosis



- mPFS values in graphic; mPFS varies between studies due to study design, inclusion/exclusion criteria and patient demographics. 5-FU=5-fluorouracil.
- 1. Burris HA et al. J Clin Oncol. 1997; 2. Conroy T et al. NEJM 2011; 3. Von Hoff et al. NEJM 2013

There is also an unmet need to prolong survival in second line treatment for patients with pancreatic cancer



- mPFS values in graphic; mPFS varies between studies due to study design, inclusion/exclusion criteria and patient demographics. 5-FU=5-fluorouracil.
- 1. Wang Gillam et al EJC 2016; 2. Oettle et al, JCO 2014; 3. Macarulla Mercade et al, Pancreas 2020; 4. Petrelli et al EJC 2017 (Iri-based)

Summary Pancreatic Cancer Benchmark for 2L PDAC Diagnosed at Metastatic Stage

Endpoint	NAPOLI-1 stage IV at diagnosis subgroup (n=61)	Meta-analysis IRI based 2L (7 studies n=396) Includes all stages at diagnosis
mOS (mos)	4.7	5.5
mPFS (mos)	3.1 (stage III-IV n=117)	2.7
ORR (%)	16%	8.7%
cORR (%)	7.7% (stage III-IV n=117)	NA
DCR (%)	52% (stage III-IV n=117)	29.4%

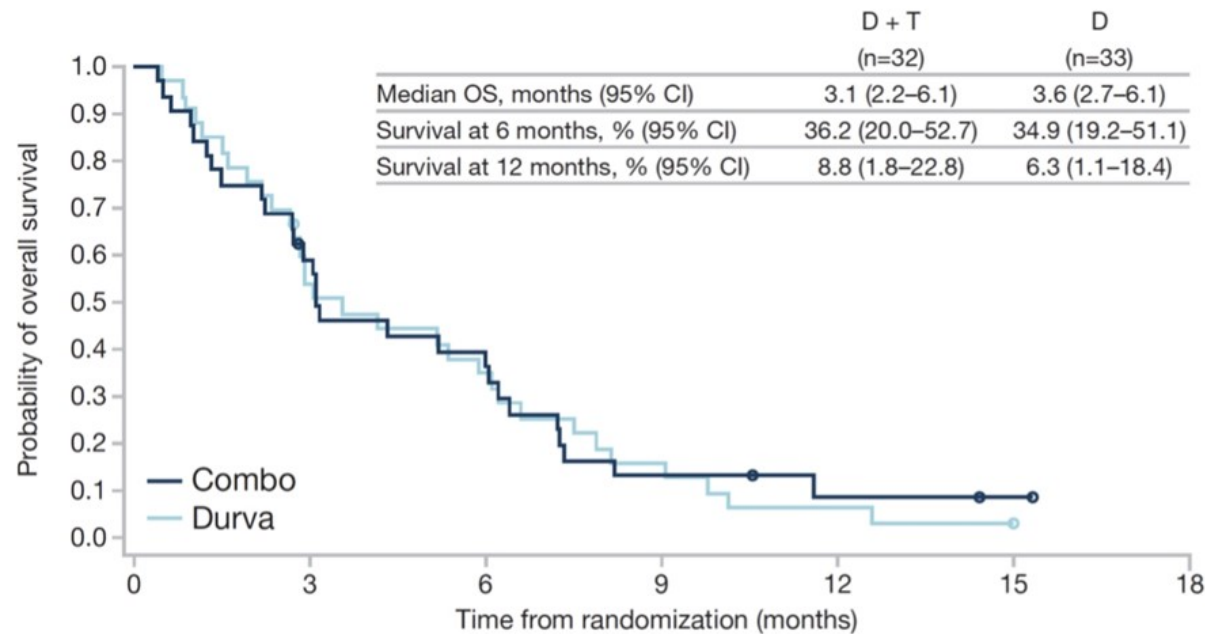
Immunotherapy in pancreatic cancer

Immunotherapy for Pancreatic Cancer

- Pancreatic cancer has been regarded as non-immunogenic
 - immunosuppressive cells and cytokines
 - low tumor mutational burden
 - paucity of T cells in tumor (number and function)?? Controversial since recent studies demonstrate that the majority of primary tumors are infiltrated with T-cells
 - efficacy of checkpoint inhibitors in PDAC was found to be absent
 - multiple immune inhibitory mechanisms in the tumor microenvironment
 - Single-agent therapeutic approaches focusing on overcoming T-cell immunologic endpoints with immune checkpoint inhibitors or vaccines are not encouraging

Royal RE, et al. *J Immunother*. 2010;33(8):828-833. Topalian SL, et al. *N Engl J Med*. 2012;366(26):2443-2454. Morrison AH et al *Trends Cancer*. 2018;4(6):418-28. Poschke I et al *Oncoimmunology*. 2016;5(12):e1240859.

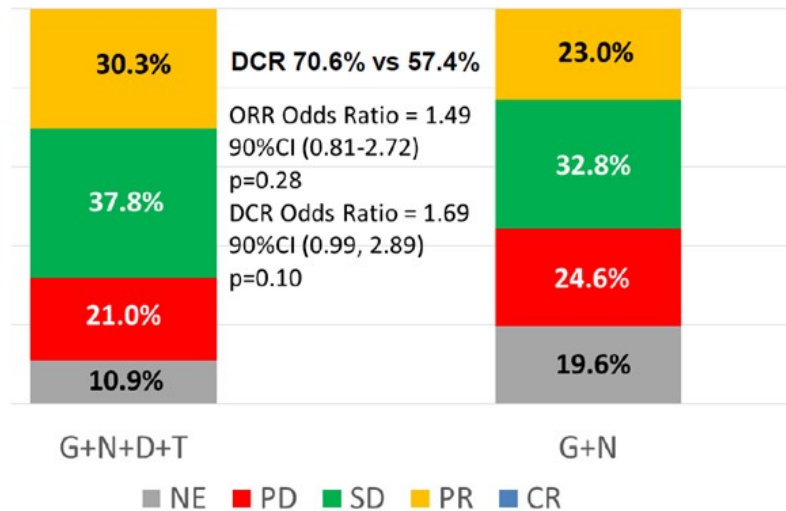
PD-1 inhibitor (durvalumab) with or without CTLA4 inhibitor (tremelimumab) in 2nd line : did not work!



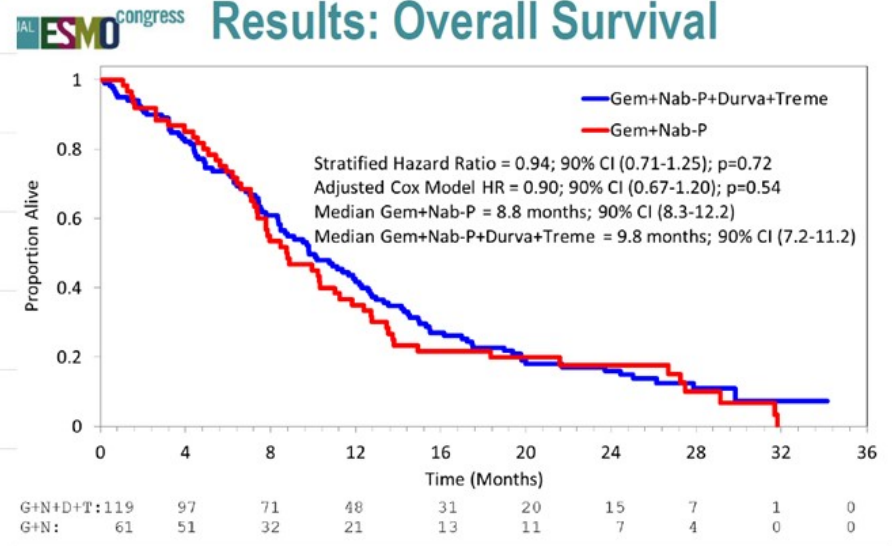
O'Reilly et al, ASCO GI, 2018

Combination of Checkpoint inhibitor and chemotherapy did not improve the chemotherapy efficacy in first line

Results: Objective Response Rate



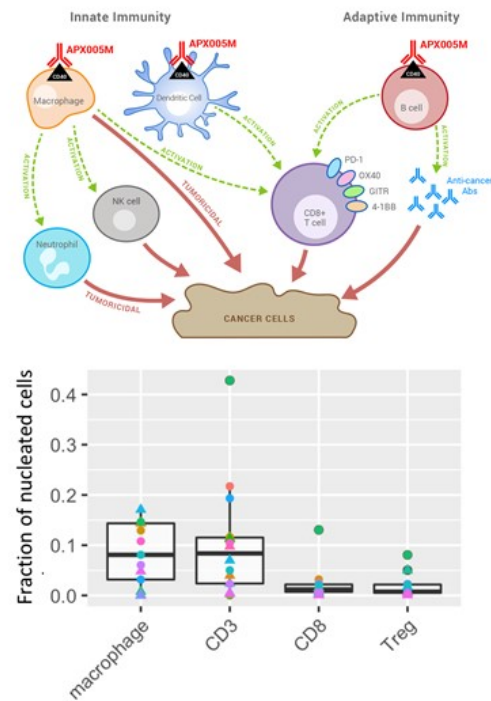
Results: Overall Survival



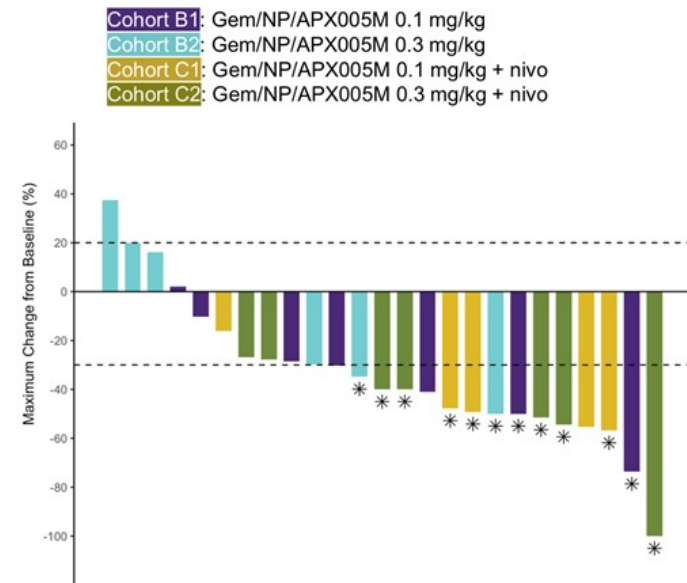
[Renouf et al, ESMO 2020](#)

Triple combination approaches are promising in PDAC

APX005M (CD40 agonist) mAb together with gemcitabine/nabpaclitaxel +/- nivolumab as 1st Line treatment



Overall response rate 54%
In all four combo 67%



O'Hara, et al, Parker Institute, AACR 2019

Summary

- Cytotoxic therapy is the mainstay of systemic therapy resulting in modest benefit in pancreatic cancer
 - Single molecule/pathway targeting is unlikely to result in significant clinical benefit
 - Single-agent therapeutic approaches focusing on overcoming T-cell immunologic endpoints with immune checkpoint inhibitors or vaccines are not encouraging
 - Immuno combinatorial therapy is the likelier strategy to succeed
 - Strong scientific rationale for which combinations is needed
 - Pancreatic cancer is a tough disease and incremental improvements are clinically meaningful
-

COMBAT Study- Cohort 2 results

Manuel Hidalgo, M.D., Ph.D. COMBAT Study Principal Investigator



December 16th 2020

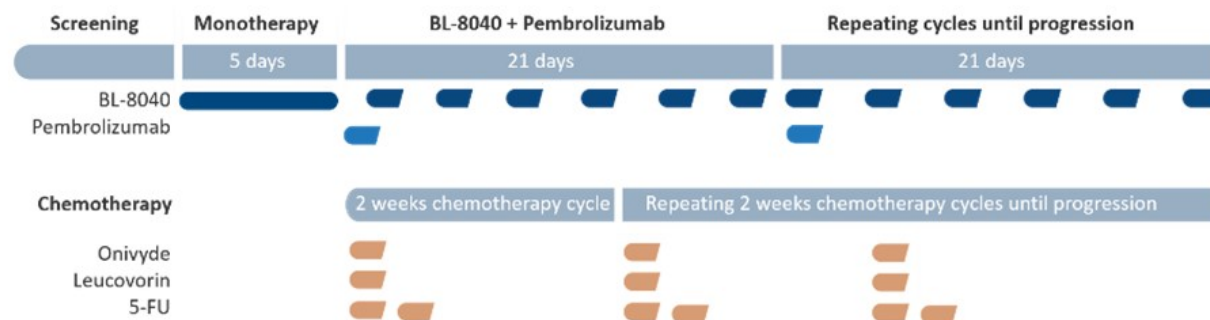
AMAZING
THINGS
ARE
HAPPENING
HERE



Disclosure

- **Founder and Stockholder:** Champions Oncology, Inc; Nelum Pharmaceuticals
- **Stockholder:** Agenus, Pharmacyte, InxMed, BioOncotech
- **Research support from:** Erytech, BioExcell, TopAlliance, PanCan
- **Honorarium from:** Agenus, Oncomatrix, InxMed, Takeda, PanCan, AACR, Tolero Pharmaceuticals.
- **Royalties:** Myriad for PALB2 patent.

COMBAT - Study Design



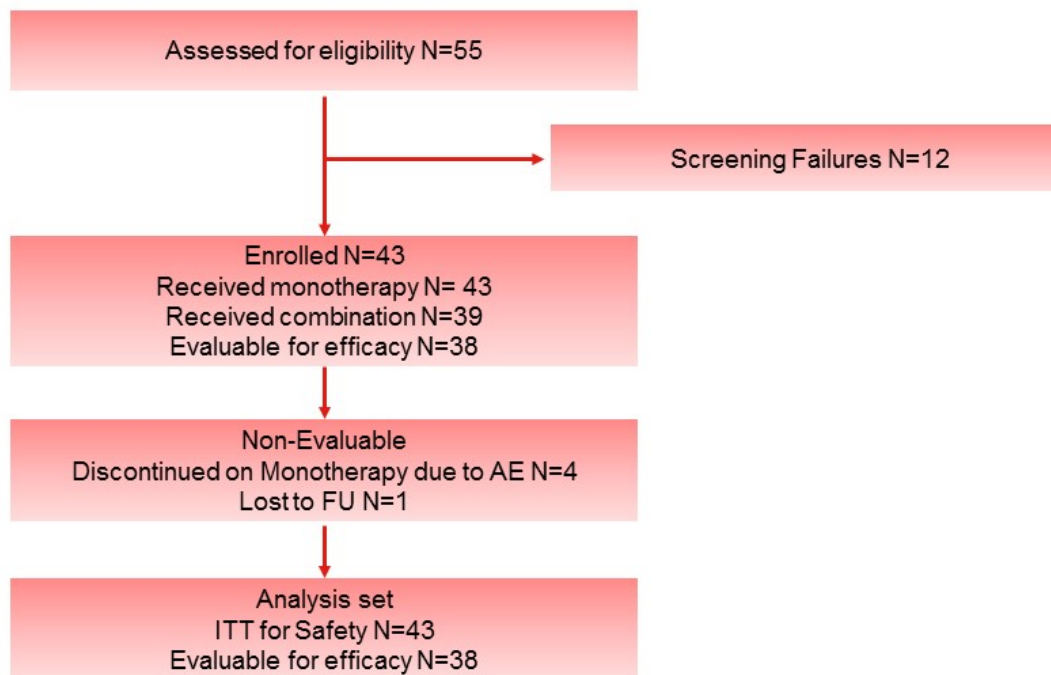
Main inclusion/exclusion criteria

- 18 years old and above
- **Metastatic disease at first diagnosis (Stage IV)**
- Progressed after first-line gemcitabine-based treatment
- No previous surgeries for PDAC, no previous locally advanced disease
- No prior PD-1 or PD-L1 treatment

Endpoints

- ORR according to RECIST 1.1 criteria
- Disease control rate (DCR)
- Duration of response
- PFS and OS
- Safety and tolerability

Disposition



Baseline characteristics

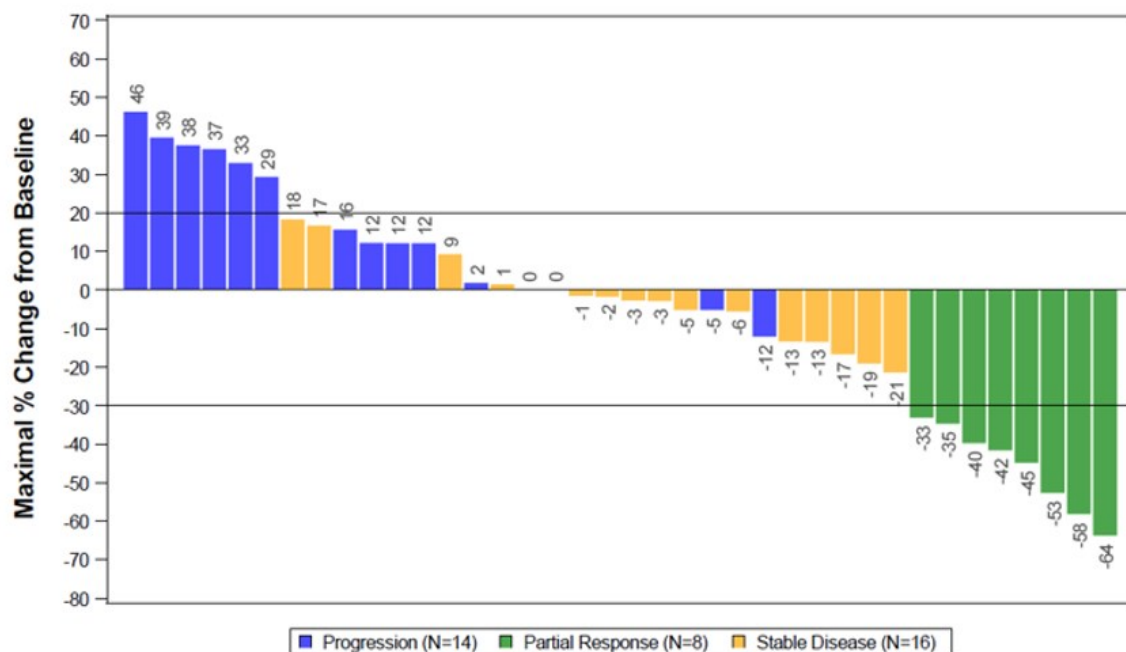
EVALUABLE	N=43
Gender	Female 44.2%/Male 55.8%
Diagnosed at stage 4	97.6%
Median age	68 (40-85)
ECOG 0/1	31.3%/68.7%
% of MSI-H (MSS status tested in 38 subjects)	0%
% of Patients with Liver Metastasis	74.4%

Safety profile

	ALL	Grade ≥ 3
Nausea and vomiting	74.4%	18.6%
Asthenia	67.4%	16.3%
Injection site reactions	55.8%	4.7%
Diarrhea	53.5%	14%
Appetite disorders	41.9%	9.3%
Pruritus	39.5%	--
Anemias	37.2%	11.6%
Rashes, eruptions and exanthems	30.2%	--
Gastrointestinal and abdominal pains	30.2%	--
Musculoskeletal and connective tissue pain and discomfort	30.2%	4.6%
Dermal and epidermal conditions	25.6%	--
Edema	23.3%	4.7%
Weight decrease	20.9%	2.3%
Hyperpigmentation disorders	20.9%	--
Gastrointestinal atonic and hypomotility disorders	20.9%	--

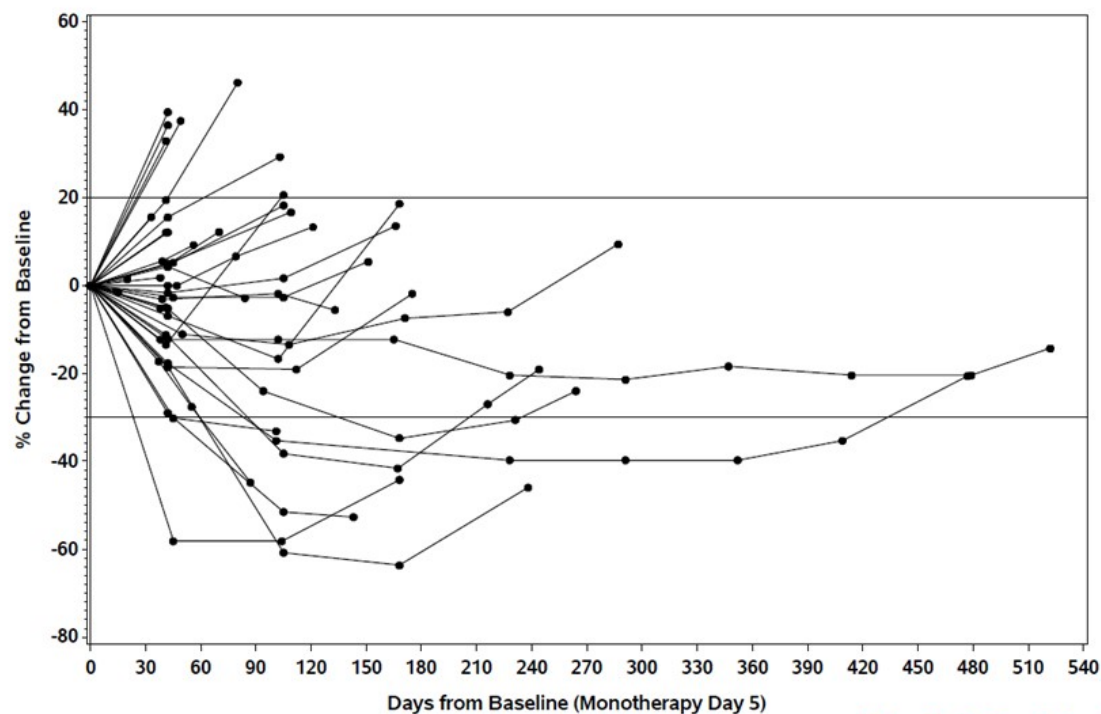
Adverse events reported in >20% of patients

COMBAT/Keynote-202 Cohort 2-Change from Baseline in Target lesions (N=38)



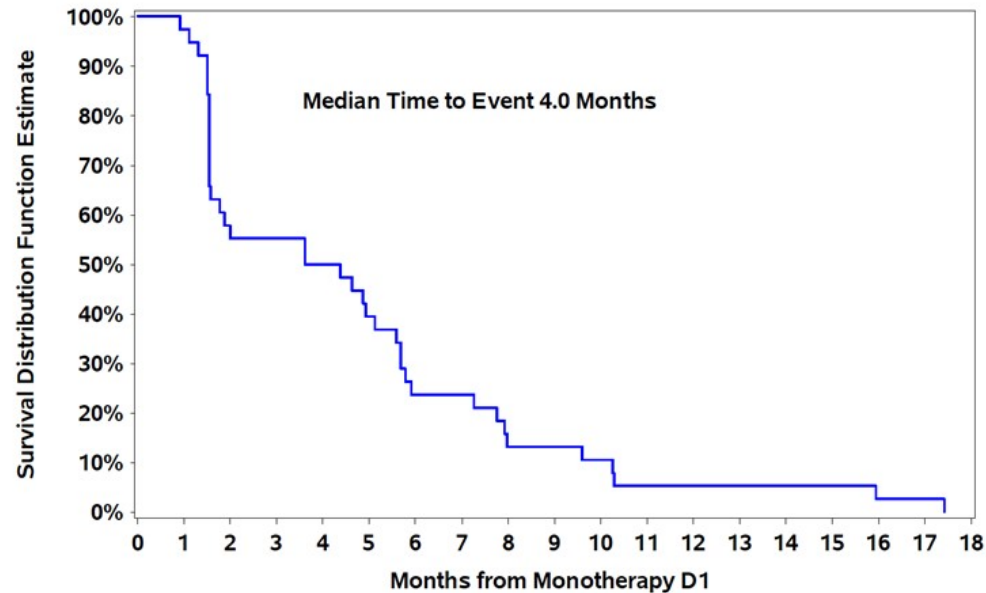
	COMBAT Cohort 2
ORR (%)	21.2%
cORR (%)	13.2%
SD	42.1%
DCR (%)	63.2%

COMBAT/Keynote-202 Cohort 2-Change from Baseline in Target lesions (N=38)

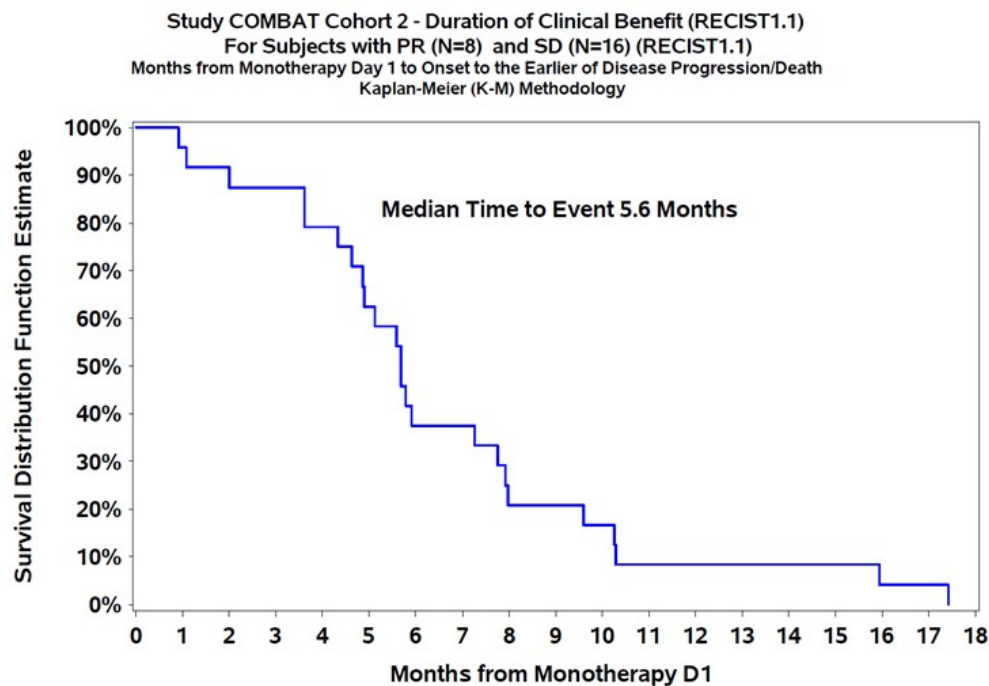


COMBAT/Keynote-202 Cohort 2 Median Progression Free Survival (mPFS) (N=38)

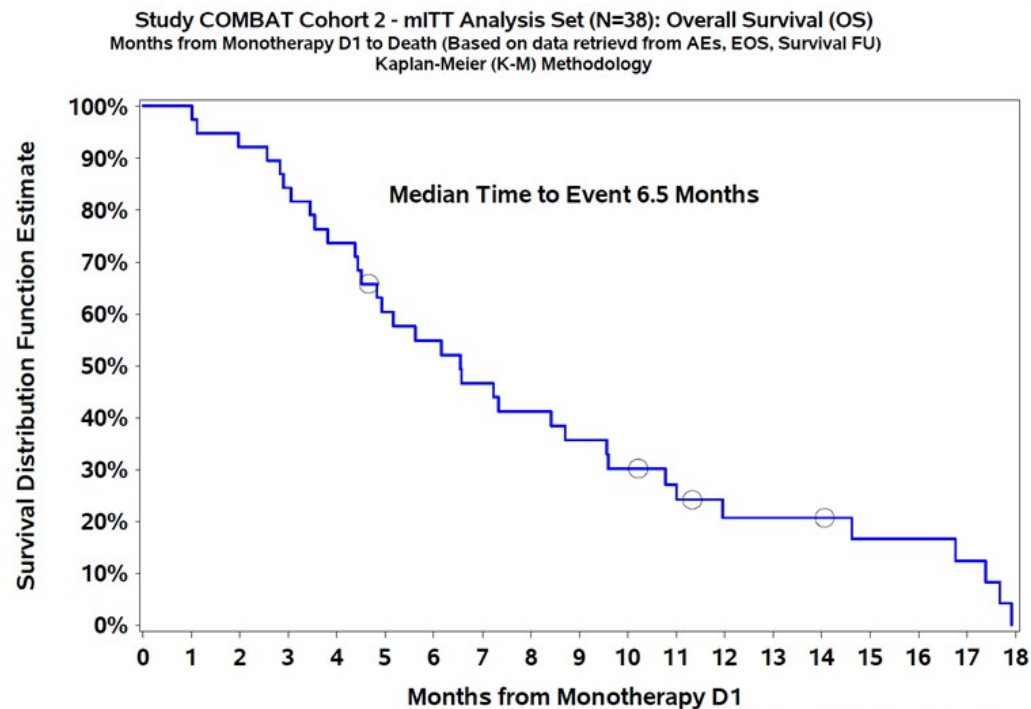
Study COMBAT Cohort 2 - mITT Analysis Set (N=38): Progression Free Survival
Months from Monotherapy D1 to the Earlier of Progression/Death (Based on data retrieved from CT Scans, AEs, EOS, Survival FU)
Kaplan-Meier (K-M) Methodology



COMBAT/Keynote-202 Cohort 2- Duration of Clinical benefit



COMBAT/Keynote-202 Cohort 2 Median Overall Survival (mOS) (N=38)



Safety- Low incidence of Neutropenia and Infections

- The triple combination was generally well tolerated
- Incidence of AEs is consistent with the profile of each drug, however
- The incidence of neutropenia and infections is lower than the expected with chemotherapy alone

	COMBAT	NAPOLI ¹
Neutropenia \geq G3	7%	20%
Infections/infestations All Grades	21%	38%
Infections/infestations \geq G3	7%	17%

https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/207793lbl.pdf

COMBAT Study Results Showed Improvement Across All Endpoints

Endpoint	COMBAT	NAPOLI-1 stage IV at diagnosis subgroup (n=61)	Meta-analysis IRI based 2L (n=396) Stage III-IV at diagnosis
mOS (mos)	6.5	4.7	5.5
mPFS (mos)	4.0	3.1 (stage III-IV n=117)	2.7
ORR (%)	21.2%	16%	8.7%
cORR (%)	13.2%	7.7% (stage III-IV n=117)	NA
DCR (%)	63.2%	52% (stage III-IV n=117)	29.4%

1. Macarulla Mercade et al, Pancreas 2020; 2. Petrelli et al EJC 2017 (Iri-based),
3. Wang Gillam et al EJC 2016;

Summary

- COMBAT Study results showed improvement across all endpoints
- Despite the triple combination regimen, the incidence of neutropenia and infection is much lower than with standard chemotherapy
- The COMBAT results are highly encouraging in light of the extremely challenging population, even among PDAC patients
- The COMBAT results strongly support further development



Q&A and Closing Remarks

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