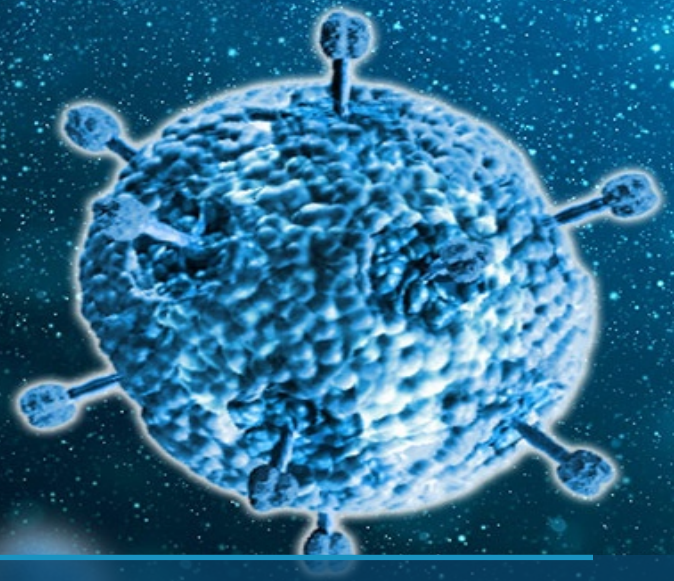
ONCOLYTICS BIOTECH INC.

Oncolytics KOL Presentation

Biomarkers & Oncolytics Viruses

April 11, 2019



oncolyticsbiotech.com **Nasdaq** ONCY **TSX** ONC

Forward Looking Statements

This presentation contains certain forward looking statements relating to the company's business prospects and the development and commercialization of pelareorep, a first-in-class systemically administered immuno-oncology agent for solid tumors and heme malignancies. These statements are based on management's current expectations and beliefs and are subject to a number of factors which involve known and unknown risks, delays, uncertainties and other factors not under the company's control which may cause actual results, performance or achievements of the company to be materially different from the results, performance or other expectations implied by these forward looking statements.

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Introductions

Dirk Arnold, MD, PhD	**Director, Asklepios Tumor Center, University Hamburg, Germany, ESMO board member**
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Kirk Look, CA	**Chief Financial Officer**
Rita Laeufle, MD, PhD	**Chief Medical Officer**
Andrew de Guttadauro	**Global Head of Business Development**
Michael Moore	**Vice President, Investor Relations & Corporate Communications**
Grey Wilkinson, PhD	**Scientist, Translational Medicine**

Agenda

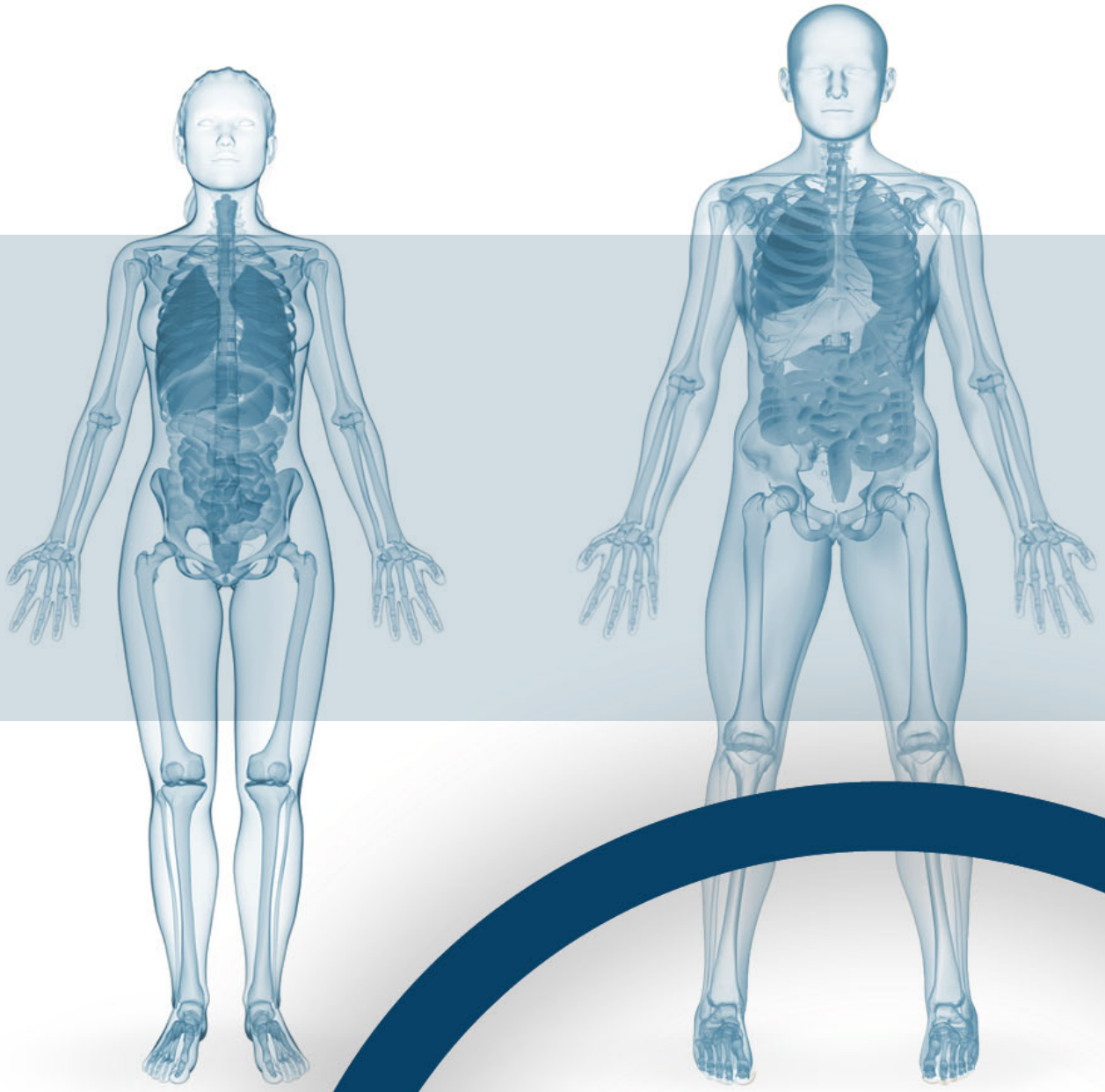
01 Pelareorep Overview

02 Biomarkers and Their Impact on Regulatory Approval

03 REO 024: Efficacy & Biomarker Data

04 Impact of Biomarkers on Clinical & Business Development

Pelareorep Overview



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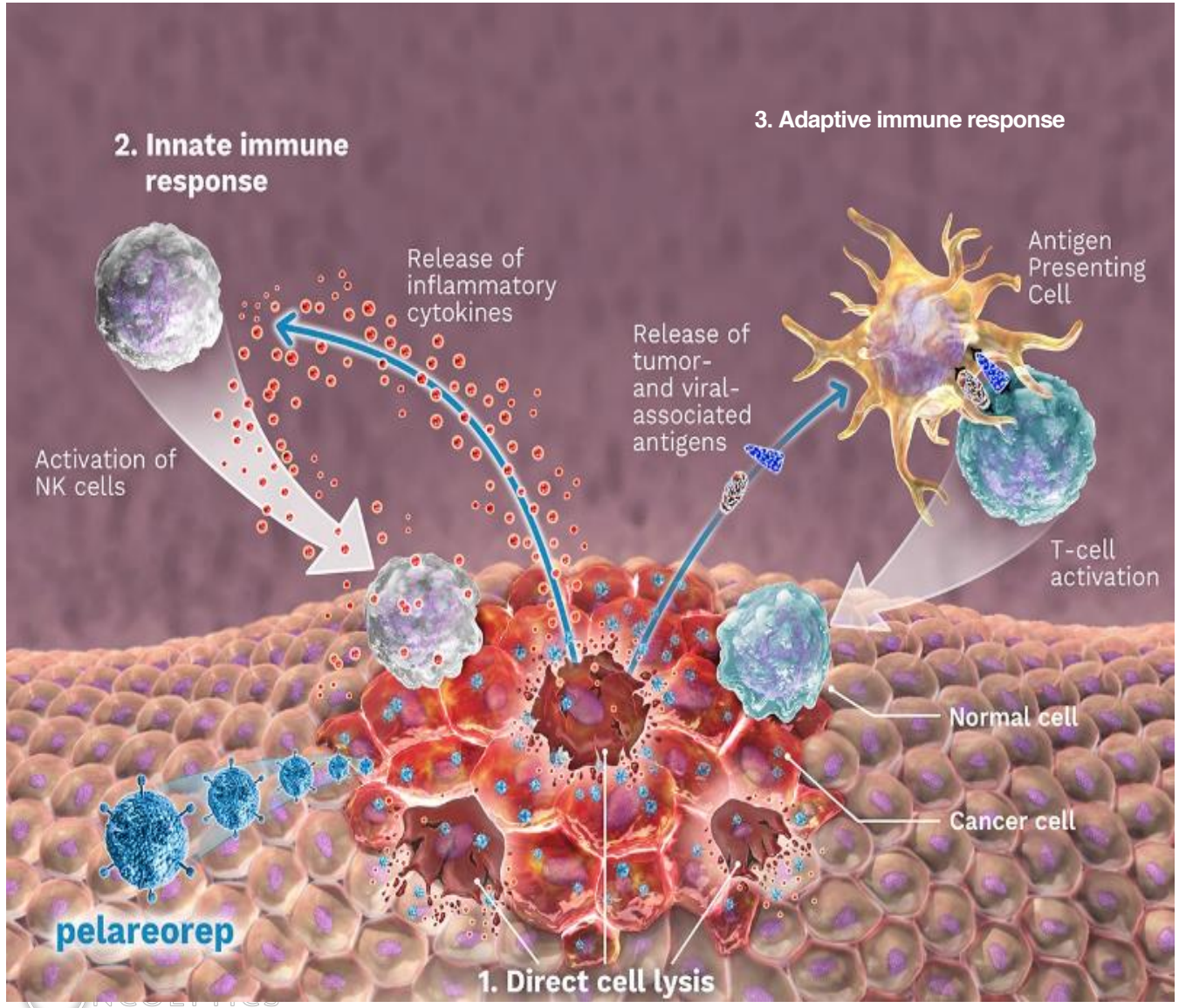
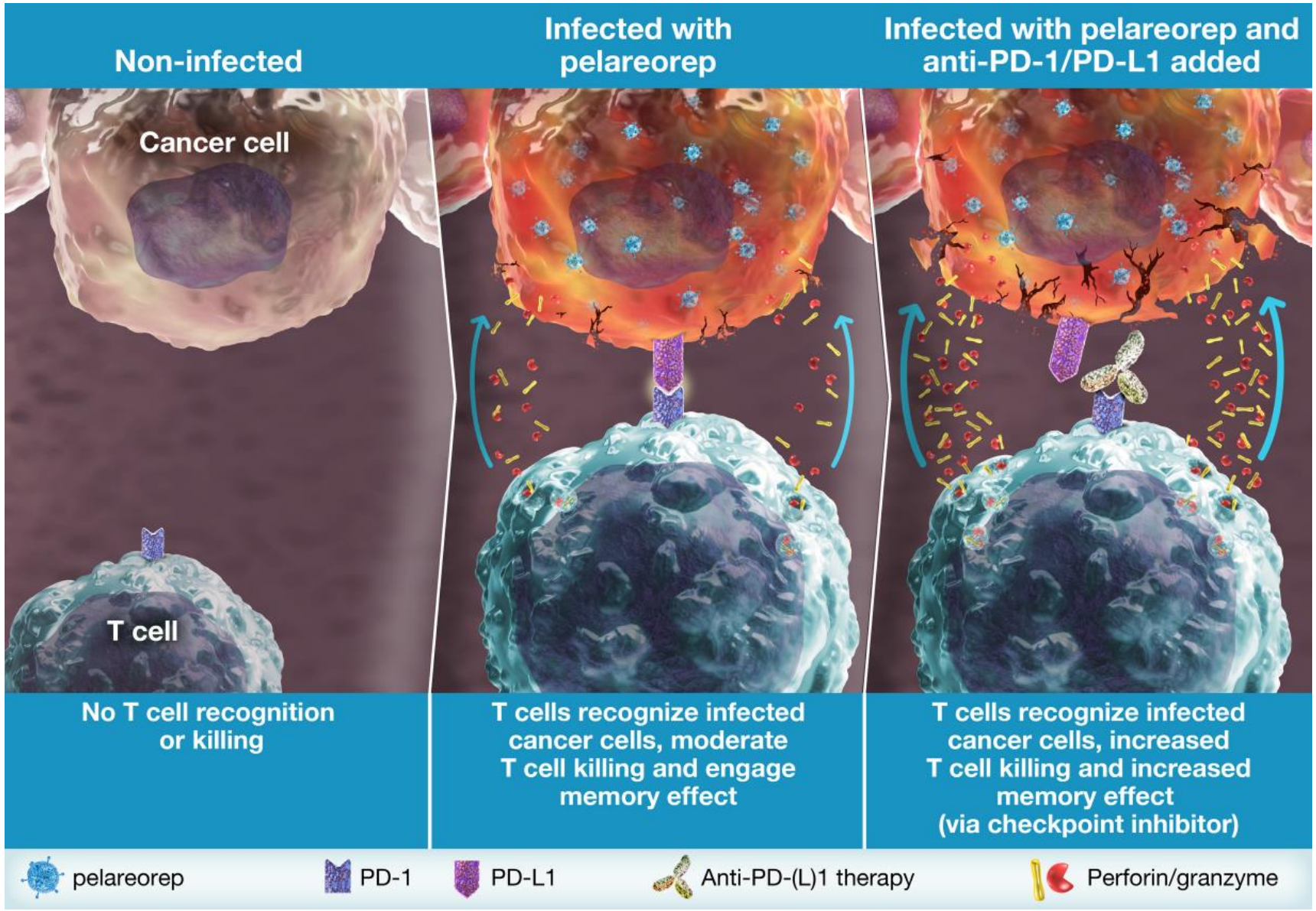
What is Pelareorep?



Non-pathogenic proprietary isolate of the unmodified reovirus

Unarmed IV delivered double stranded RNA (dsRNA) oncolytic virus that creates an inflamed phenotype in tumor tissue

Pelareorep at a Glance: Immune Stimulation

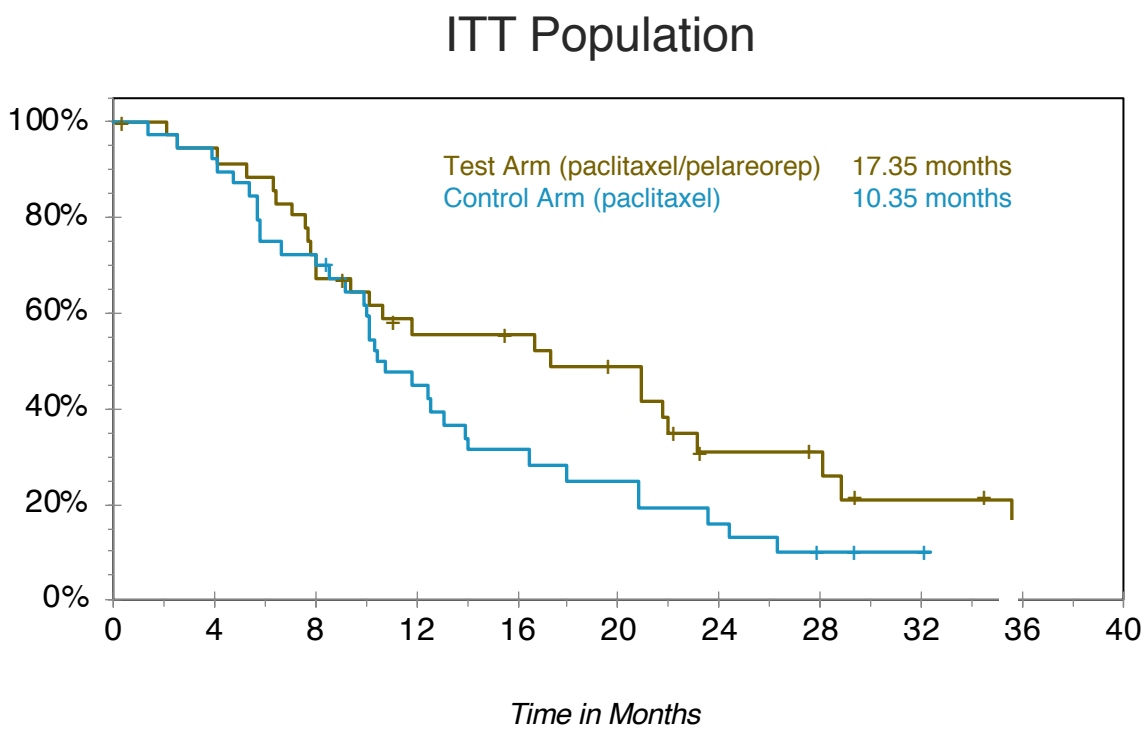


Pelareorep at a Glance: Efficacy and Safety

1,100+ patients treated, 900+ intravenously

No maximum tolerated dose (MTD) reached to date

First **IV delivered immuno-oncolytic virus** to demonstrate **overall survival** benefit in a randomized study in metastatic breast cancer

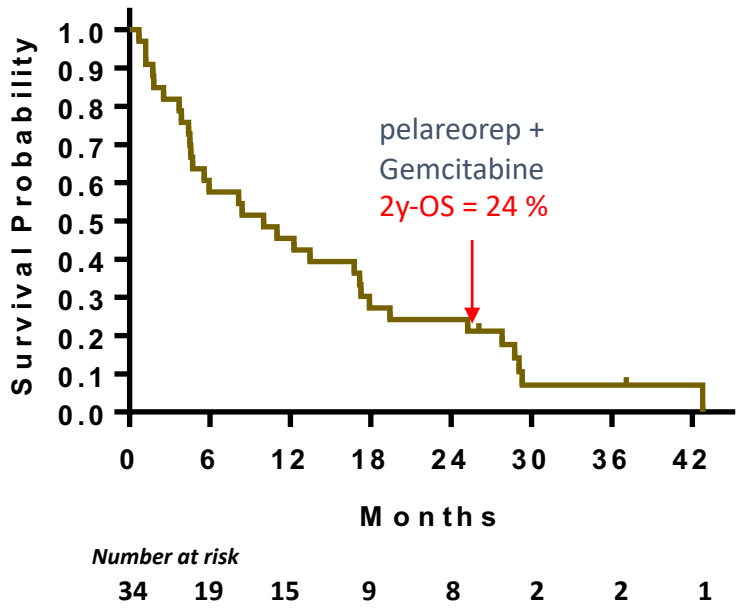


Bernstein V et.al. Abstract CT131, AACR 2017

Pelareorep treatment has shown an enhanced overall survival benefit across cancer indications

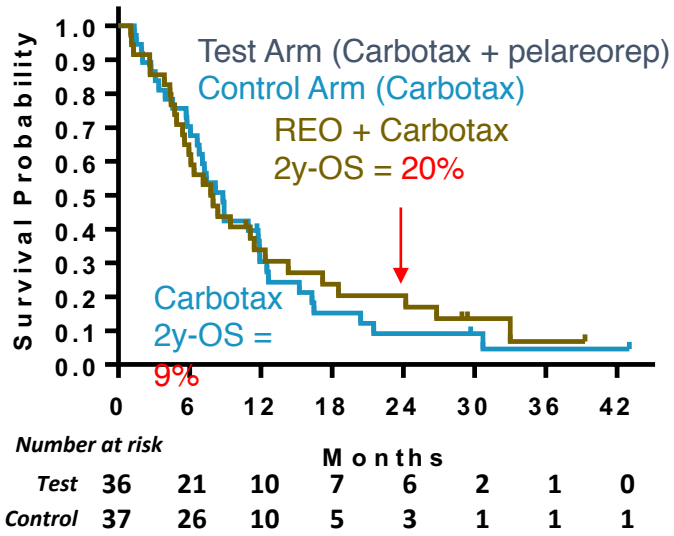
Tolerable and safe with encouraging benefit in 2y-survival in single arm Ph 2 studies:

Overall survival in REO-017 Single Arm Pancreatic Cancer study

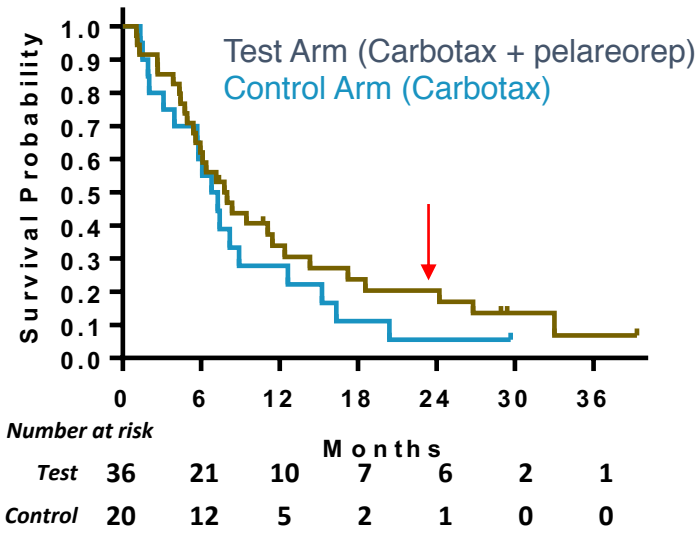


Overall survival in NCI-8601, Randomized Pancreatic Cancer study

All patients, N= 73



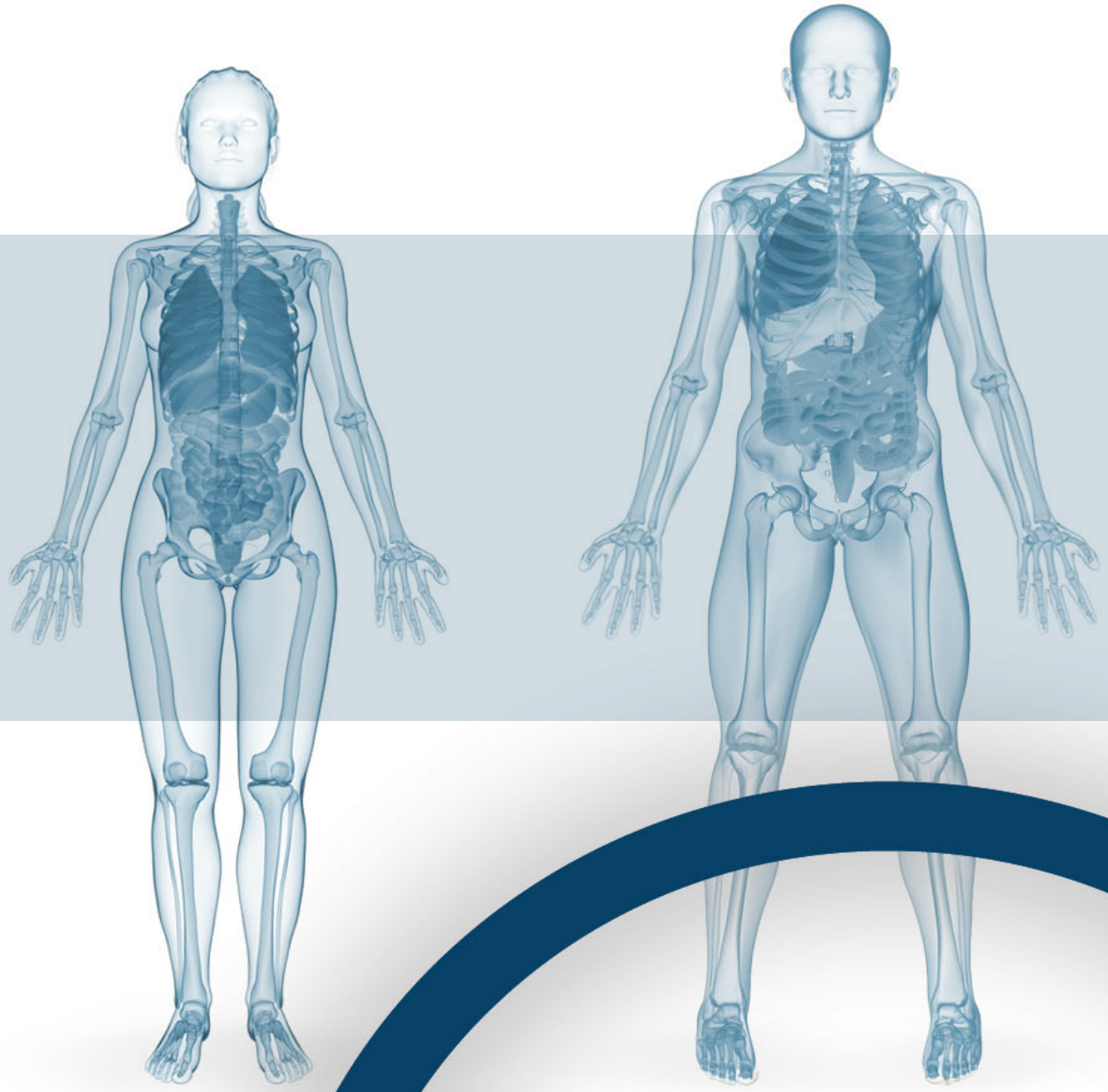
Excluding crossover patients, N= 56



Systemically delivered pelareorep in combination with chemotherapy achieves 1 & 2 year-survival rates of 46% & 24% in pancreatic cancer patients

Mahalingam *et al.* ESMO, 2015, P-175. and Noonan *et al.* Molecular Therapy, 2016, 24:1150–11.

Biomarkers and Their Impact on Regulatory Approval



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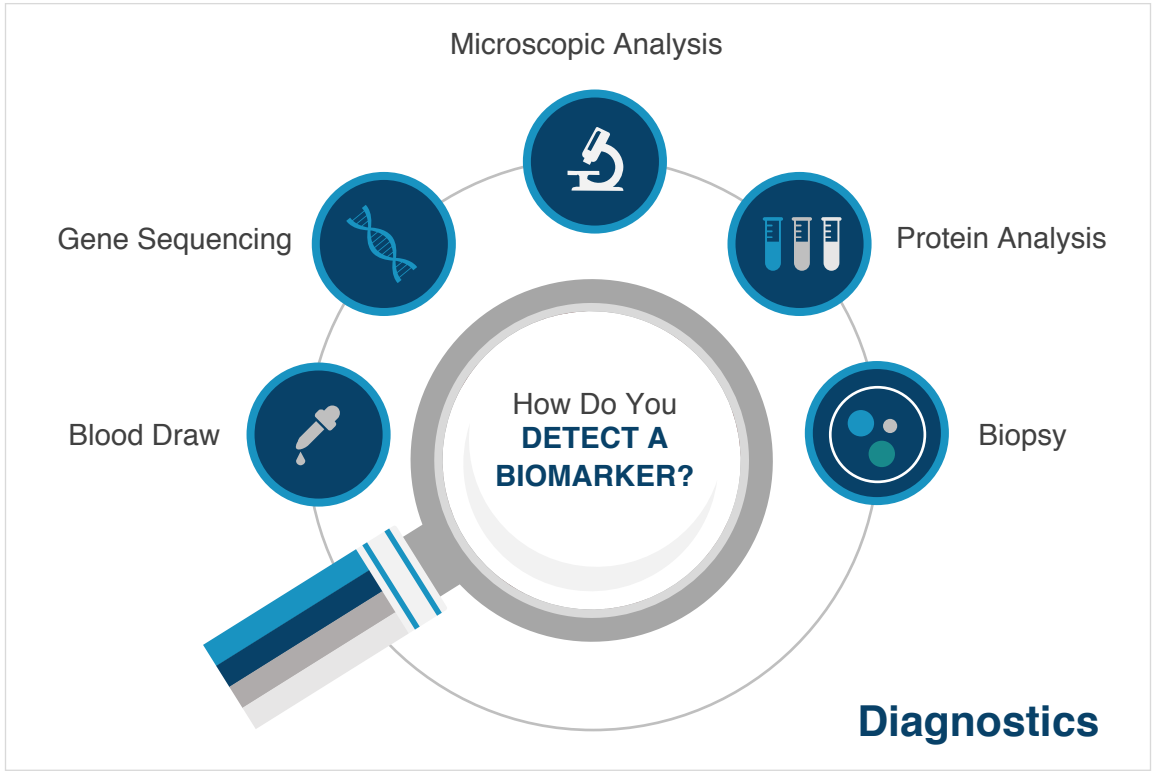
What is a Biomarker and Why is a Biomarker Important

A biomarker is an indicator of biological processes or a characteristics that either:

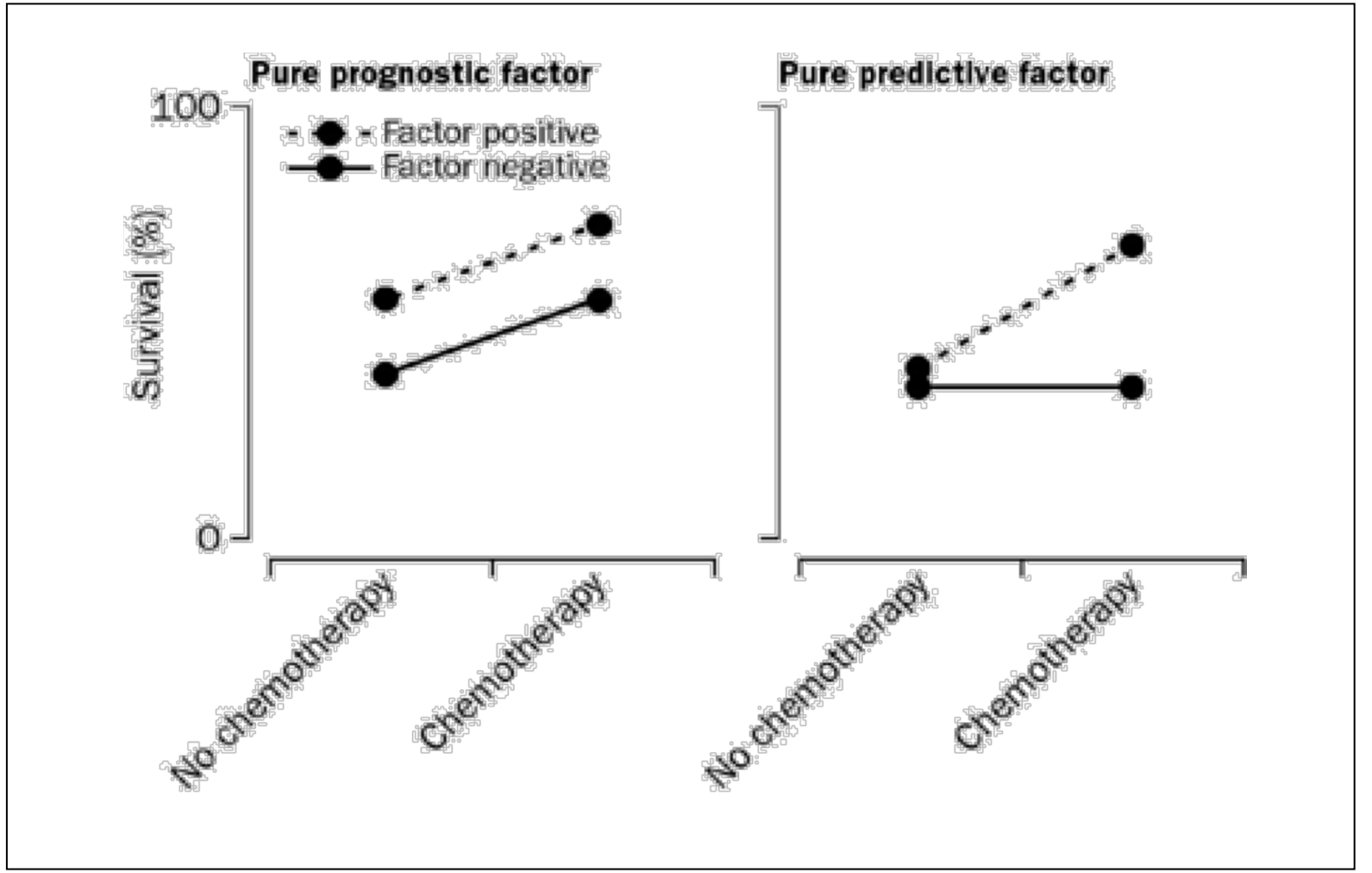
- Can identify or characterize a disease or its severity or prognosis
- Can identify patients that may need a specific treatment
- May serves as a guide to optimize treatment
- Is subject to change during a disease or an intervention
- Can be used as surrogate endpoint in clinical studies to accelerate approval of a new compound



The **importance** of **biomarkers** continues to grow in all areas of clinical practice and, whether to predict, diagnose, or monitor disease, **biomarkers** are useful and important in every step of patient care!

Graph source: http://www.fda.gov/BiomarkerQualificationProgram

Prognostic Versus Predictive



Barratt et al., Lancet 2002

FDA: Biomarker Evaluation Program

*"…**we need a whole new generation of biomarkers** that are more informative and that can tell developers earlier whether or not their drug may have toxicity or …..may not work at all, **and to get that early read on what's going to be successful.** And so those biomarkers are ones that have yet to be developed".*

- J. Woodcock FDA

Susan McCune, MD, Center for Drug Evaluation and Research, FDA:

"Biomarker-based strategies allow for a more biology-targeted approach to drug development and may enable time and cost savings through leaner, more focused clinical trials that have a higher overall probability of success with respect to both efficacy and safety."

"Biomarkers can be used to identify the mechanism of action of a drug…"

"FDA recognizes biomarker development as a high priority area for future research and collaboration among stakeholders and is taking action to better understand biomarkers used in drug development."

Source: https://www.youtube.com/watch?v=Q1CwARpnfe8 & https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/BiomarkerQualificationProgram/ucm539845.htm

The Importance of Biomarkers in Clinical Studies

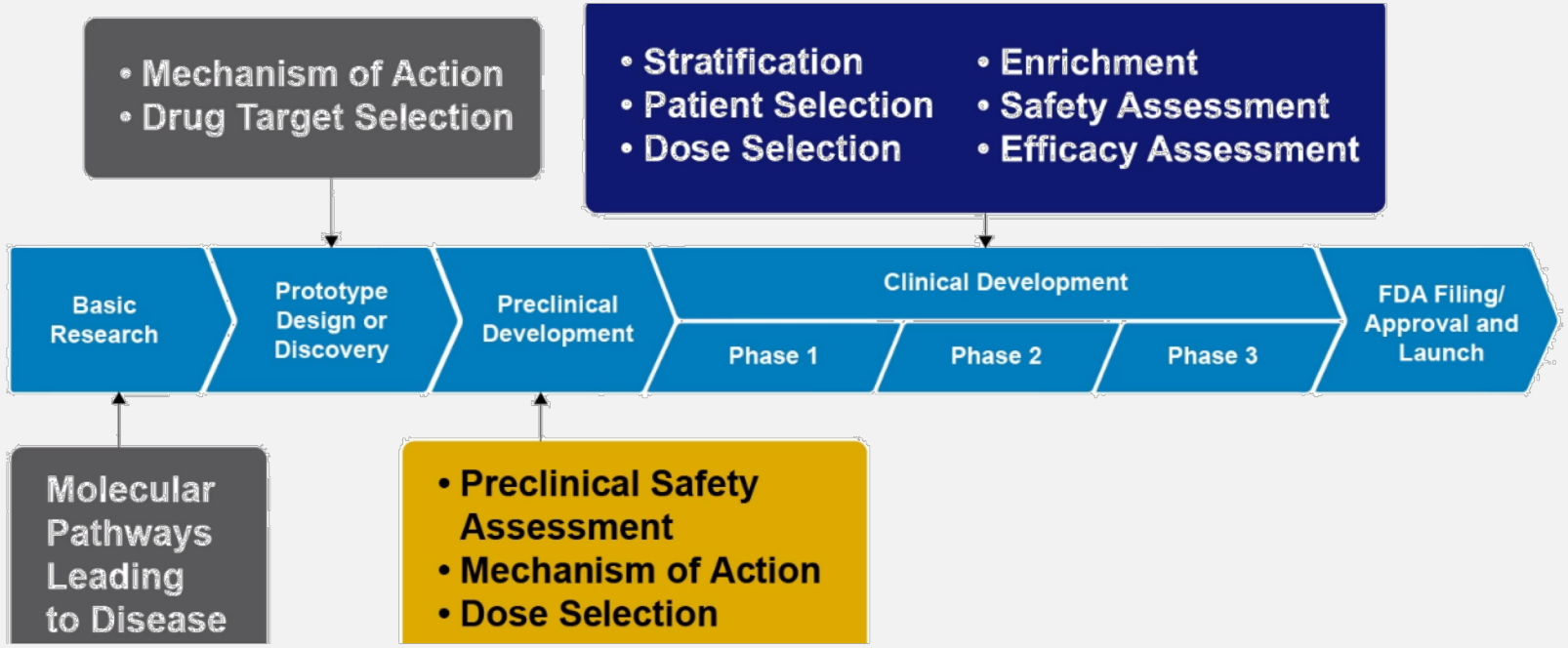
Conventional clinical study approach:

Is using clinical outcomes such as survival or disease progression. Collection of information on these endpoints take many years…..

Biomarker-driven clinical study approach:

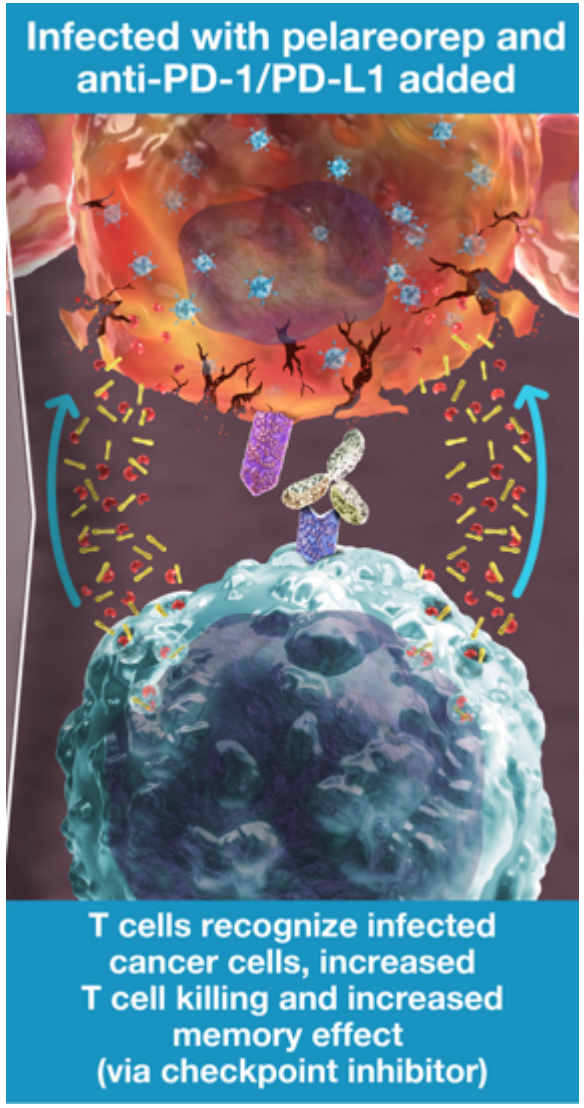
may **predict drug efficacy more quickly** than conventional endpoints.

"Potential to accelerate product development"



Source: https://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugDevelopmentToolsQualificationProgram/BiomarkerQualificationProgram/ucm539845.htm

Next Generation: Biomarker-guided Personalized Medicine



On-Treatment Biomarker: Influence on Clinical Treatment Decisions

On-treatment biomarkers

- offer the potential for **monitoring** of treatment response, treatment-associated toxicity, and onset of treatment resistance
- markers for response to available cancer therapies move treatment toward a **fully individualized** therapeutic approach
- can be detected in **blood or in tissue**

Tarhini et al, Dec 2018 Cancer Treatment, Volume 71, pages 8-18. Predictive and on-treatment monitoring biomarkers in advanced melanoma: Moving toward personalized medicine: https://www.cancertreatmentreviews.com/article/S0305-7372(18)30159-2/fulltext

On-Treatment Biomarker: Influence on Clinical Treatment Decisions

Phase II, non comparative, study

Target accrual: 27 pts

CRICKET

mCRC pts
RAS and *BRAF* wt

FOLFIRI/
FOLFOXIRI
+ Cetuximab

PD

FOLFOX/XELOX/
FOLFOXIRI
+ Bevacizumab

PD

Irinotecan
+ Cetuximab

→ ORR 22%
→ DCR 54%

≥ 6 Months

- At least a RECIST 1.1 partial response
- 1st-line PFS ≥6 months
- PD to 1st-line cetuximab within 4 weeks after the last cetuximab administration

≥ 4 Months

- Time between the end of 1st-line therapy and the start of 3rd-line ≥4 months

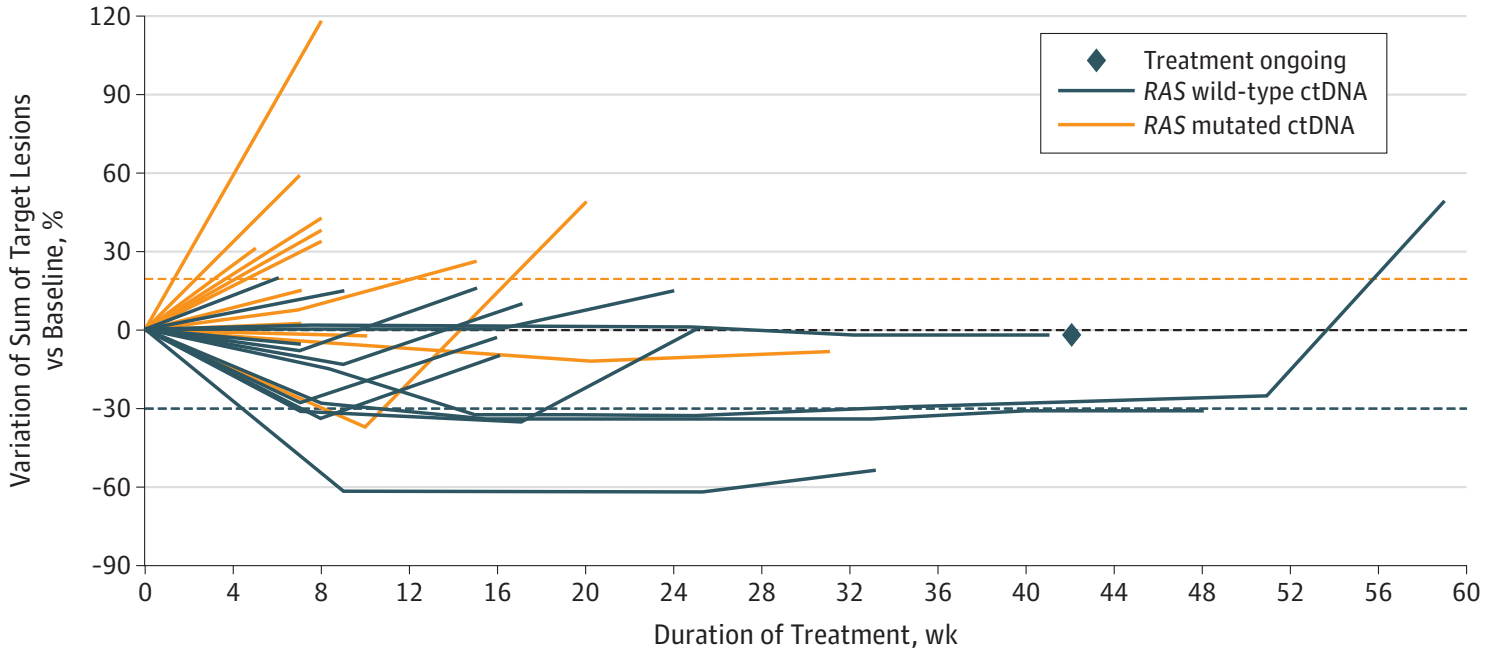
Study treatment:
Irinotecan 180 mg/sqm iv
Cetuximab 500 mg/sqm iv

ctDNA for RAS/BRAF mutations (ddPCR+NGS)

Rossini et al., ASCO 2018

On-Treatment Biomarker: Influence on Clinical Treatment Decisions

CRICKET trial: Phase 2 single-arm study of re-challenge with cetuximab + irinotecan as 3rd-line therapy in *RAS* and *BRAF* WT pts with acquired resistance to 1st-line cetuximab- and irinotecan-containing therapy



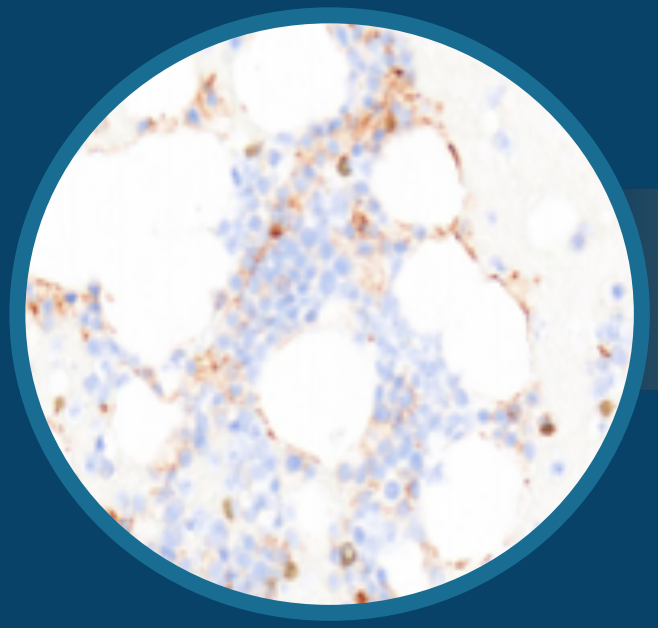
Cremolini C, et al. JAMA Oncol 2019; 5:343-350.

ctDNA, circulating tumor DNA

On-Treatment Effect

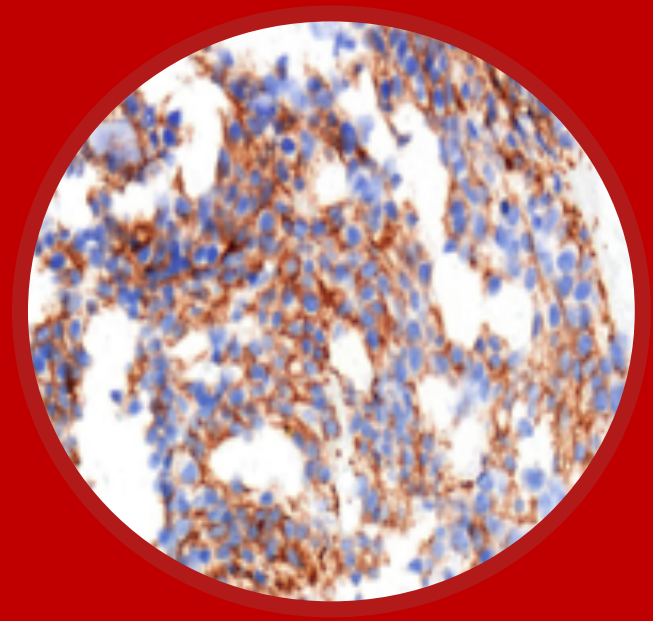
Pelareorep's Promotion of an Inflamed Phenotype

Pre-treatment
Lack of PD-L1 staining



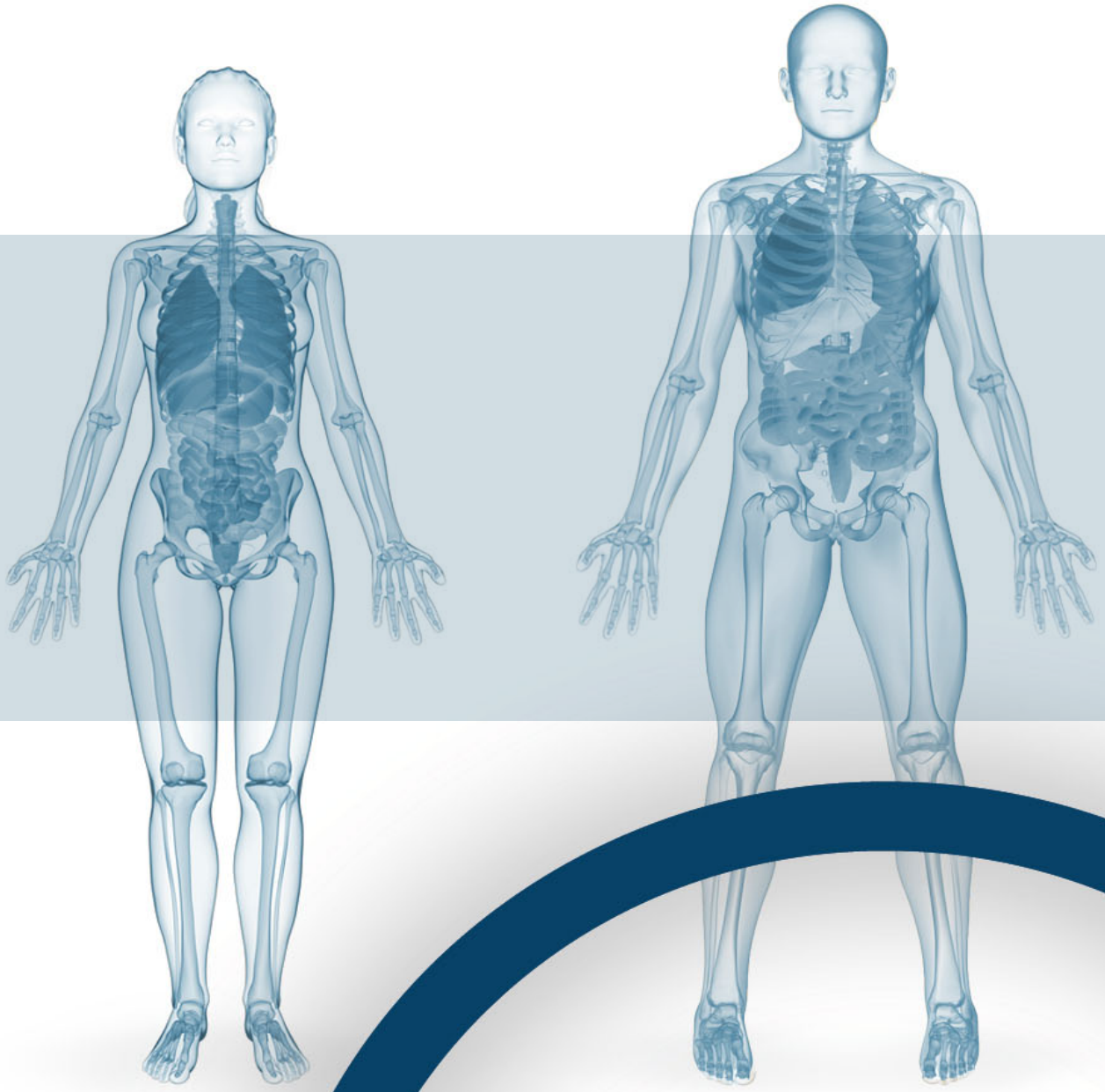
7-8 Days

One week after pelareorep + carfilzomib
>90% PD-L1 staining



REO 024:
Efficacy & Biomarker Data

A Phase Ib study of pembrolizumab in combination with pelareorep and chemotherapy in patients with advanced pancreatic adenocarcinoma



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Detailed results were presented last week at AACR

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Exploratory analysis of T cell repertoire dynamics upon systemic treatment with the oncolytic virus pelareorep in combination with pembrolizumab and chemotherapy in patients with advanced pancreatic adenocarcinoma (Abstract #2272)

Grey A. Wilkinson[1], Devalingam Mahalingam[2], Sukeshi Patel Arora[3], Paul A. Fields[4], Patrick Raber[4], Karol Cheetham[1], Matt Coffey[1].

[1]Oncolytics Biotech Inc., Calgary, AB and San Diego, CA; [2]Northwestern University, Chicago, IL; [3]UT Health San Antonio, San Antonio, TX; [4]Adaptive Biotechnologies, Seattle, WA

Abstract

Background: Pelareorep is an immuno-oncolytic virus that induces an inflamed tumor phenotype in metastatic adenocarcinoma of the pancreas (MAP). Systemically delivered pelareorep in combination with chemotherapy achieves 1 & 2 year-survival rates of 46% & 24% in MAP patients (pts), respectively[1]. Analysis of tumor tissue from pts treated with pelareorep, chemotherapy and anti-PD-L1 have shown reovirus RNA and protein replication, T cell infiltration, and upregulation of PD-L1, highlighting that effective T cell recognition of tumor antigens may be critical to success for this combination therapy[2]. Thus, we hypothesized that pelareorep in combination with chemotherapy and pembrolizumab in pts with MAP would alter the peripheral T cell repertoire, creating new T cell clones via the release of novel neoantigens in addition to expanding existing T cell clones.

Methods: A phase 1b study enrolled 11 MAP pts who progressed after first-line treatment. Pts received pelareorep (4.5e10 $TCID_{50}$ IV, D1 & D2), plus pembrolizumab (2 mg/kg IV, D8) plus either 1) 5-FU (LV 200 mg/m^2, 5-FU 200 mg/m^2 IV bolus, 5-FU 1200mg/m^2 continuous IV infusion D1) or 2) gemcitabine (1000 mg/m^2 IV, D1), or 3) irinotecan (125 mg/m^2 IV, D1) q3w, until disease progression/unacceptable toxicity. DNA from peripheral blood mononuclear cells from nine patients at cycle 1 day 1 (C1D1) & C2D1 (approx. 3 weeks later) was analyzed using the immunoSEQ® Assay (Adaptive Biotechnologies, Seattle) sequencing the T cell receptor beta chain region to interrogate changes in the T cell repertoire.

Results: The median Morisita index between C2D1 and C1D1 was 0.83 with three samples below 0.6, indicative of significant peripheral repertoire turnover. The median number of expanded clones equated to 45.7 per 100,000 cumulative templates; normal variation over 4 weeks is ~ 5-10 expanded clones. Strikingly, most (median: 86%) peripheral clonal expansion occurred in clones below the limit of detection at C1D1. Cox regression analysis revealed that high peripheral clonality correlates with progression free survival at C1D1 (HR = 0.053, p = 0.01). Moreover, high clonality correlates with overall survival at both C1D1 (HR = 0.124, p = 0.013) and C2D1 (HR = 0.079, p = 0.010).

Conclusions: High levels of peripheral T cell repertoire turnover occur between C1D1 and C2D1. Repertoire turnover is accompanied by significant clonal expansion, mostly by expansion of new clones (i.e. undetected in C1D1). Higher peripheral clonality is associated with better progression free survival at C1D1, and overall survival at C1D1 and C2D1. This research highlights the potential utility of T cell clonality as a predictive and prognostic biomarker to pelareorep therapy and warrants further clinical investigation.

Background

Study Design and Schedule[2]

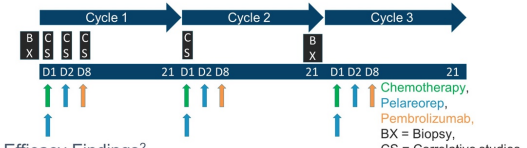
2L Relapsed Metastatic Adenocarcinoma of the Pancreas (MAP)
n = 11

→

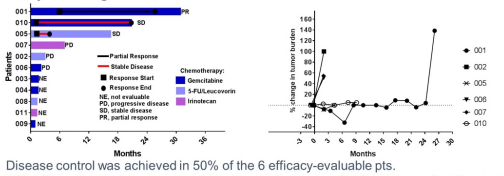
21 day cycle:
- pelareorep 4.5x10^{10} $TCID_{50}$ IV
- Pembrolizumab 2 mg/kg IV
- Gemcitabine or 5-flurouracil or irinotecan

→

Primary endpoint:
•Dose-limiting toxicities
Secondary Endpoints: ORR, PFS, OS, biomarkers



Efficacy Findings[2]



- Disease control was achieved in 50% of the 6 efficacy-evaluable pts.
- Of 6 efficacy evaluable pts, one achieved partial response (PR) 197 days after the start of therapy that has lasted 17.4 months.
- Two additional pts achieved stable disease (SD) 57-59 days on therapy, lasting 277 and 126 days, respectively.
- Nine pts have died secondary to progressive to disease (PD).

Background cont.

Safety Findings[2]

Treatment was safe and tolerable in all patients without an increase in Grade 4 toxicity (n = 11).

Preferred Term	Any grade	Grade 1/2	Grade 3	Grade 4
Any event, n (%)	10 (90.1)	10 (90.1)	1 (9.1)	1 (9.1)
Fever	9 (81.8)	8 (72.7)	1 (9.1)	0
Chills	6 (54.5)	5 (45.5)	1 (9.1)	0
Fatigue	3 (27.3)	3 (27.3)	0	0
Headaches	3 (27.3)	3 (27.3)	0	0
Anemia	2 (18.2)	2 (18.2)	0	0
Emesis	2 (18.2)	2 (18.2)	0	0
Flu-like Symptoms	2 (18.2)	2 (18.2)	0	0
Hypotension	2 (18.2)	2 (18.2)	0	0
Nausea	2 (18.2)	2 (18.2)	0	0
Neutropenia	2 (18.2)	2 (18.2)	0	1 (9.1)
Leukopenia	1 (9.1)	0	0	1 (9.1)

Treatment-related adverse events occurring at any grade in ≥ 10% of patients or grade ≥ 3 in any patient

Study Hypothesis

We hypothesized that pelareorep in combination with chemotherapy and pembrolizumab in pts with MAP would alter the peripheral T cell repertoire, specifically we asked:
- If pelareorep (oncolytic virus) treatment creates novel T cell clones via release of neoantigens, or
- If pelareorep treatment expands existing T cell clones.

Methods

Immuno sequencing of the CDR3 regions of human TCRβ chains was performed using the ImmunoSEQ® Assay developed by Adaptive Biotechnologies, Seattle, WA. DNA for this assay was isolated from PBMCs collected at cycle 1 day 1 (C1D1), C1D8, and C2D1. Diversity is calculated as Shannon's Entropy by:

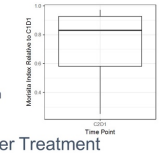
$$Diversity = H = -\sum_{i=1}^{N} p_i \log_2(p_i)$$

Where p_i is the proportional abundance of clone i, and N is the total number of unique receptor gene rearrangements. Clonality is defined as 1 − Pielou's evenness metric and is calculated by 1 − $H/\ln(N)$. Where indicated, Simpson Clonality is defined as $\sqrt{\sum p_i^2}$ where p_i is the frequency of each rearrangement in the repertoire.

Results

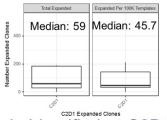
Low Morisita Indices Between C1D1 and C2D1 Suggests High Repertoire Turnover

- Morisita Index takes into account both repertoire overlap and clonal frequencies between the two samples. A perfectly identical repertoire is 1, and two completely disparate samples would be 0.
- Normal variation over a month is ~0.9– 0.95.
- The median Morisita between C2D1 and C1D1 is 0.83 with 3 samples below 0.6. This suggests significant peripheral repertoire turnover.



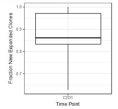
Significant Peripheral Clonal Expansion Over Treatment

- Peripherally expanded clones were determined between C1D1 and C2D1.
- Normal variation over 4 weeks is ~ 5-10 expanded clones.
- Median values are greater than 40 in both cases. Only 1 sample had less than 18 expanded clones



Most Peripherally Expanded Clones are Newly Identified at C2D1

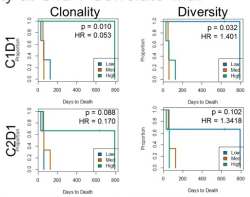
- Peripherally expanded clones can be either expansion of existing clones or newly identified clones (i.e. undetected in the first time point).
- Most peripheral clonal expansion is observed from new clones (Median: 86%).



Results cont.

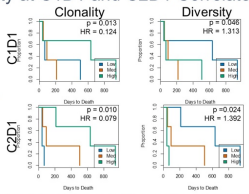
Peripheral Clonality and Diversity at C1D1 Correlate with Progression Free Survival

- Variables were treated as continuous variables for cox regression.
  - Clonality was scaled to a unit of 0.1
  - Diversity was scaled to a unit of 100
- Clonality and diversity are correlated with progression free survival and show a stronger p-value at C1D1.
- Higher peripheral clonality and lower diversity are associated with longer progression free survival.



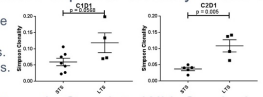
Peripheral Clonality and Diversity at C1D1 and C2D1 Correlate with Survival Time

- Variables were treated as continuous variables for cox regression.
  - Clonality was scaled to a unit of 0.1.
  - Diversity was scaled to a unit of 100.
- Clonality and diversity are correlated with overall survival and show a stronger p-value at C2D1.
- Higher peripheral clonality and lower diversity are associated with better outcome.

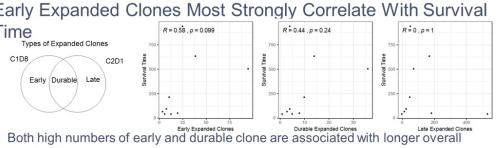


Long Term Survivors Have Greater Peripheral Clonality at C2D1

- Responders and long term survivors have greater peripheral Clonality at C2D1.
  - Long term survivors (LTS): > 6 months.
  - Short term survivors (STS): < 6 months.



Early Expanded Clones Most Strongly Correlate With Survival Time



- Both high numbers of early and durable clone are associated with longer overall survival times.
- The strongest correlation is seen with the number of early expanded clones.
- Early vs. late clonal expansion may be influenced by the type of response pelareorep is eliciting.

Conclusion

- Higher peripheral clonality and lower diversity are associated with better overall survival.
- High levels of peripheral repertoire turnover occur between C1D1 and C2D1.
- Repertoire turnover is accompanied by significant clonal expansion, mostly by increases in "new" clones (clones that were undetected in C1D1).
- The number of early expanded clones (prior to pembrolizumab) is associated with longer overall survival. There is no correlation with either durable or late expanded clones and clinical outcome.
- A study by Hopkins *et al*. has also shown that peripheral T cell repertoire associates with survival in MAP pts treated with nivolumab and a pancreatic cancer vaccine[3].

References

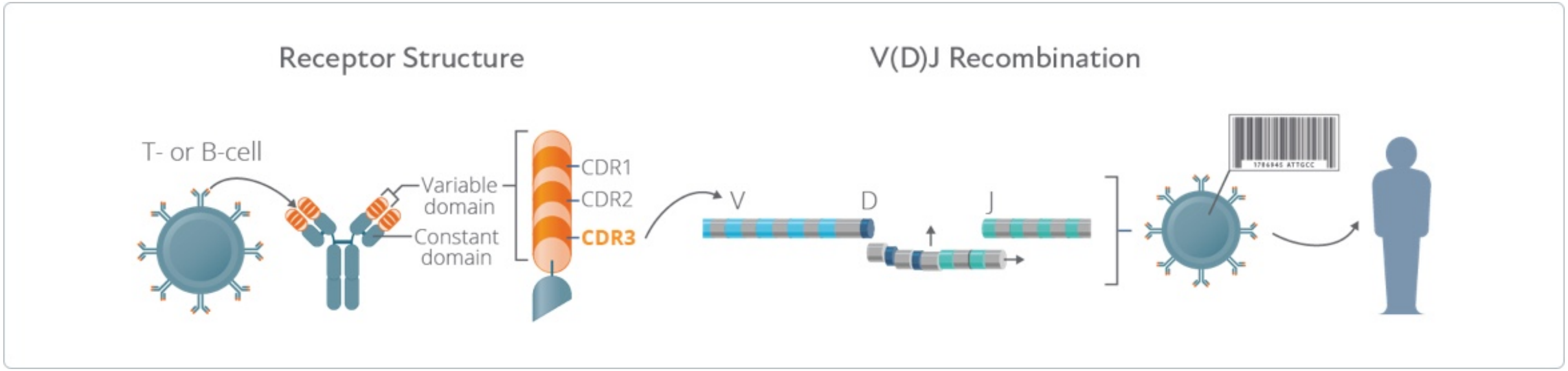
1. Mahalingam, D., et al., *A Phase II Study of Pelareorep (REOLYSIN(R)) in Combination with Gemcitabine for Patients with Advanced Pancreatic Adenocarcinoma.* Cancers (Basel), 2018. 10(8).
2. Mahalingam, D., et al., *A study of REOLYSIN in combination with pembrolizumab and chemotherapy in patients (pts) with relapsed metastatic adenocarcinoma of the pancreas (MAP).* J Clin Oncol 35, (suppl; abstr e15753), 2017.
3. Hopkins, A.C., et al., *T cell receptor repertoire features associated with survival in immunotherapy-treated pancreatic ductal adenocarcinoma.* JCI Insight, 2018. 3(13).

See poster online:

Characterizing T Cell Clonality with immunoSEQ®

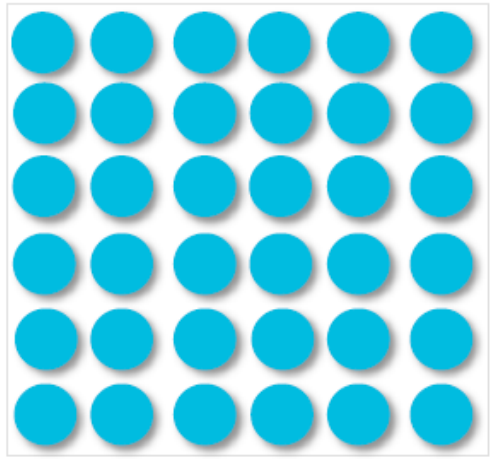
T cell receptors (TCRs) contain both constant and variable domains

- The variable domains confer antigen specificity and allow the adaptive immune system to continually recognize new targets
- Within the variable domain, the most highly variable region is the CDR3 and this is what we target for immune repertoire sequencing
- The immunoSEQ assay allows for the quantification of clonality



Source: Adaptive Biotechnologies

Clonal Expansion or Clonality is a Critical Marker of Immune Activation

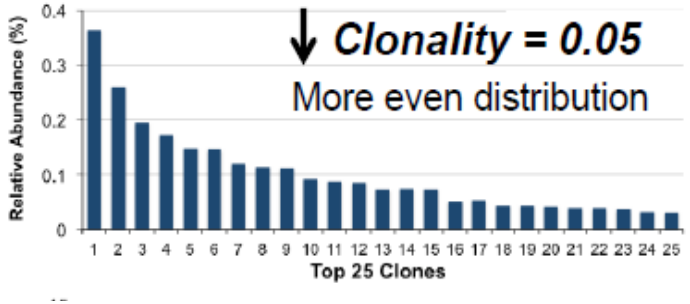


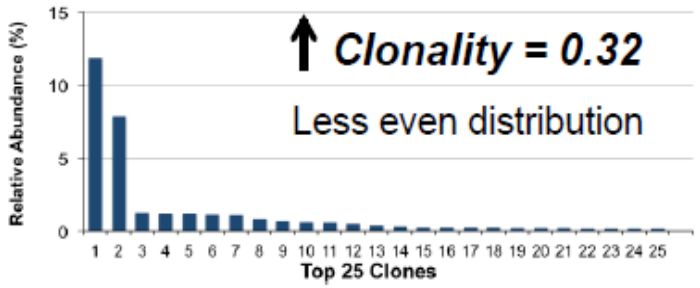
Purely diverse = 0

Monoclonal = 1

- Clonality indicates how evenly distributed the abundances of unique clones are in a sample.
- Values range on a scale from 0 to 1

Relative abundance of top 25 clones in a sample:





A Phase 1b Study of Pembrolizumab in Combination with Pelareorep and Chemotherapy in Patients with Advanced Pancreatic Adenocarcinoma

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Hypothesis:

Pelareorep in combination with chemotherapy and pembrolizumab alters the peripheral T cell repertoire.

- Does pelareorep create novel T cell clones via release of neoantigens?

and/or

- Does pelareorep expand existing T cell clones ?

2L Relapsed Metastatic Adenocarcinoma of the Pancreas (MAP)
n = 11

21 day cycle:

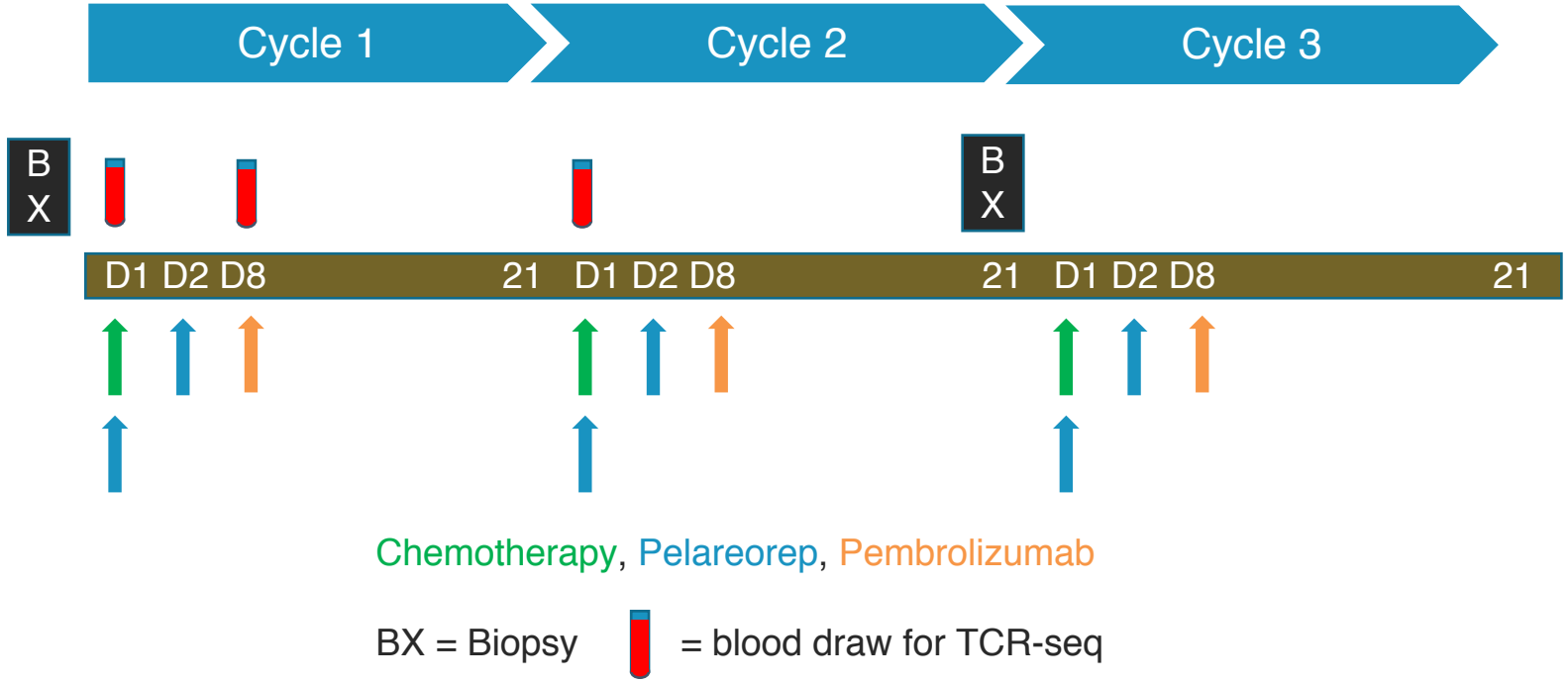
- pelareorep 4.5x^{10} $TCID_{50}$ IV
- Pembrolizumab 2 mg/kg IV
- Gemcitabine or 5-flurouracil or irinotecan

Primary endpoint:

- Dose-limiting toxicities

Secondary Endpoints:

- ORR
- PFS
- OS
- biomarkers

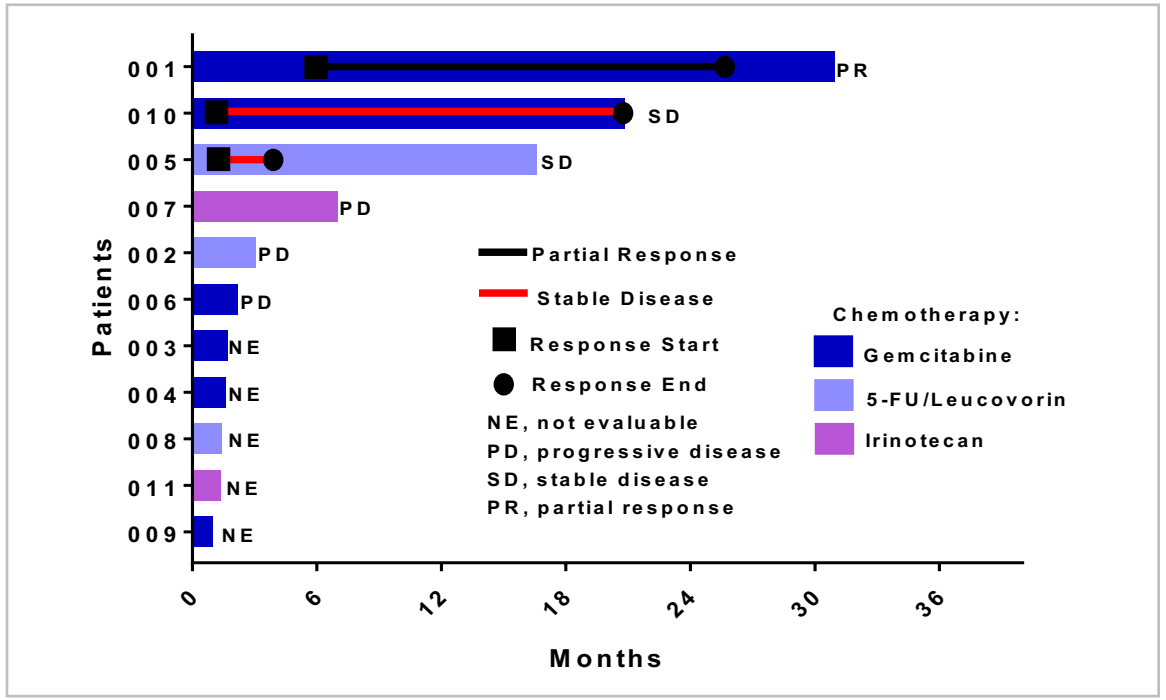


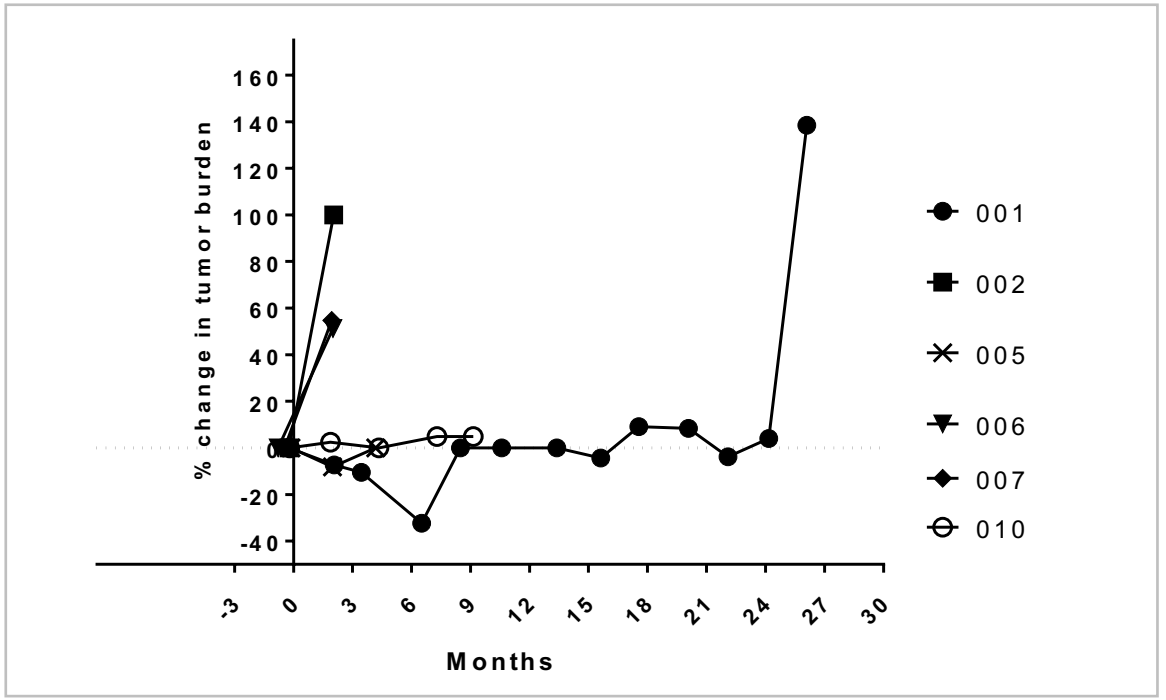
A Phase 1b Study of Pembrolizumab in Combination with Pelareorep and Chemotherapy in Patients with Advanced Pancreatic Adenocarcinoma

Efficacy findings

6 efficacy evaluable patients:

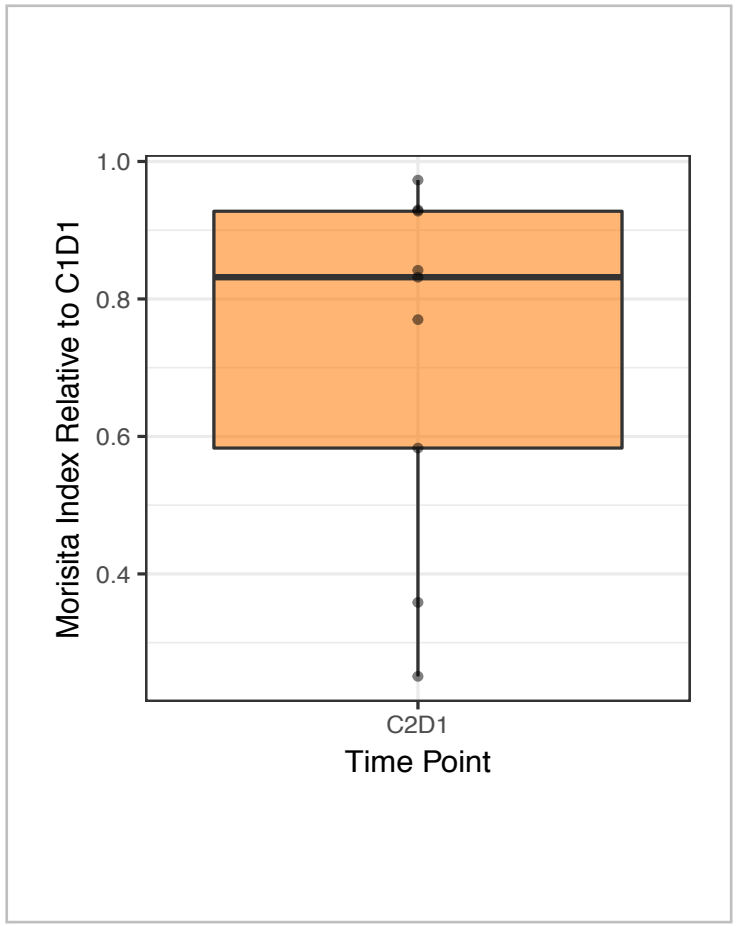
- One patient: Partial Response (PR), starting 6.5 mos. after the start of therapy, lasting 17.4 mos.
- Two patients: Stable Disease (SD), for 6 and 9.5 mos. respectively

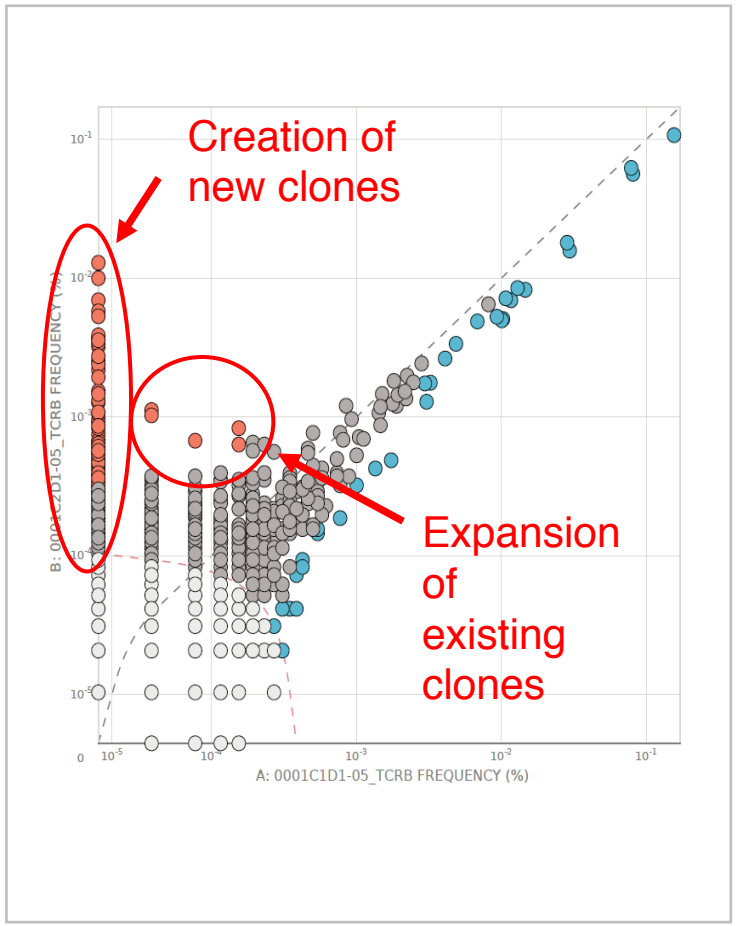




Disease control was achieved in **50%** of the 6 efficacy-evaluable patients

Low Morisita Indices Over Time Suggests High Repertoire Turnover with Significant Creation of New Clones





- Morisita Index (MI)
  - takes into account both repertoire overlap and clonal frequencies between the two samples.
  - A perfectly identical repertoire is 1, and two completely disparate samples would be 0.
  - Normal variation over a month is ~0.9–0.95.

Between baseline and c2 d1:

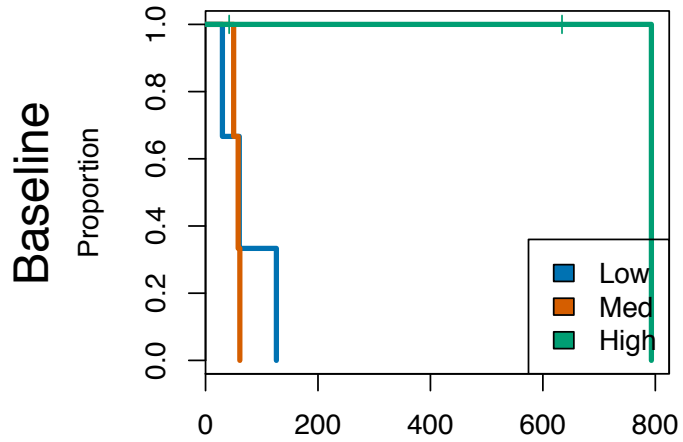
- Median MI is 0.83 - with 3 samples below 0.6. This suggests significant peripheral repertoire turnover.
- 86% of peripheral clonal expansion is observed from new clones

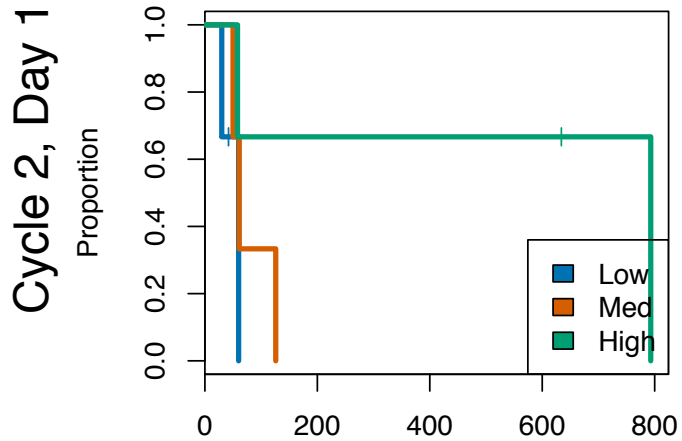
→ indicative of T cell priming.

Peripheral Clonality at Baseline: Correlates with Progression Free Survival

- Variables were treated as continuous variables for cox regression
  - Clonality was scaled to a unit of 0.1
- Clonality is correlated with progression free survival and show a stronger p-value at baseline
- Higher peripheral clonality is associated with longer progression free survival

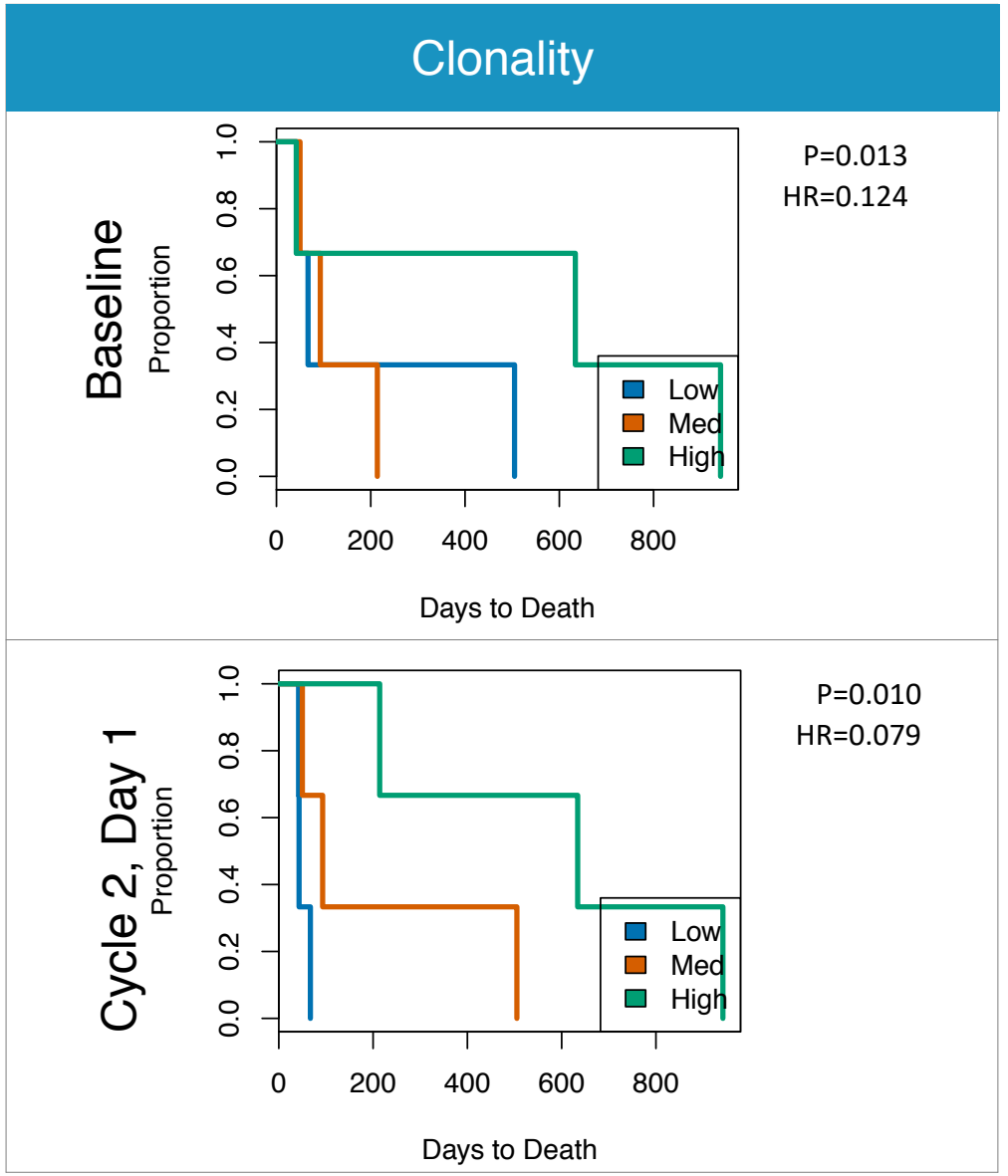
Clonality





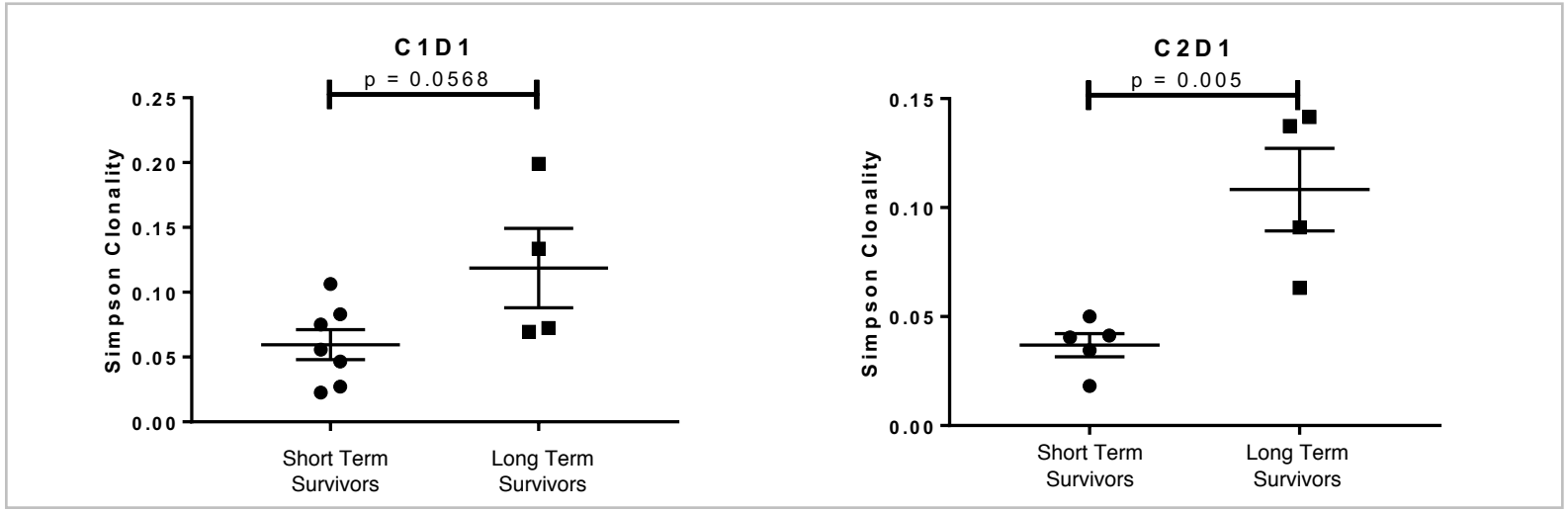
Peripheral Clonality at Baseline: Correlates with Overall Survival

- Variables were treated as continuous variables for cox regression.
  - Clonality was scaled to a unit of 0.1
- Clonality is correlated with overall survival and show a stronger p-value at cycle two, day 1.
- Higher peripheral clonality is associated with better outcome.



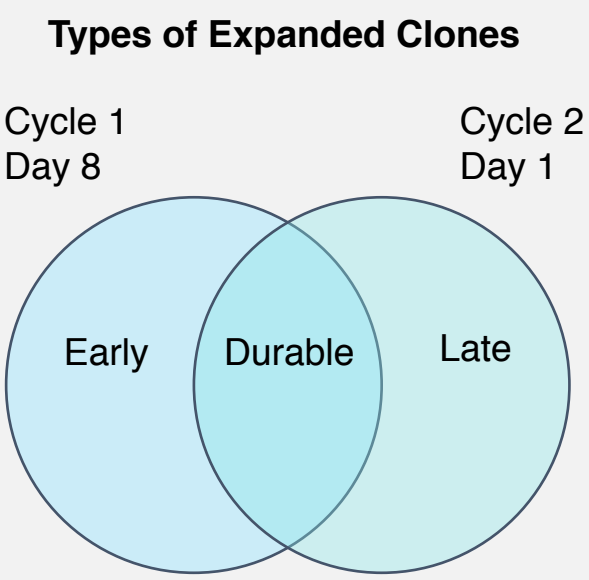
Long Term Survivors Have Greater Peripheral Clonality

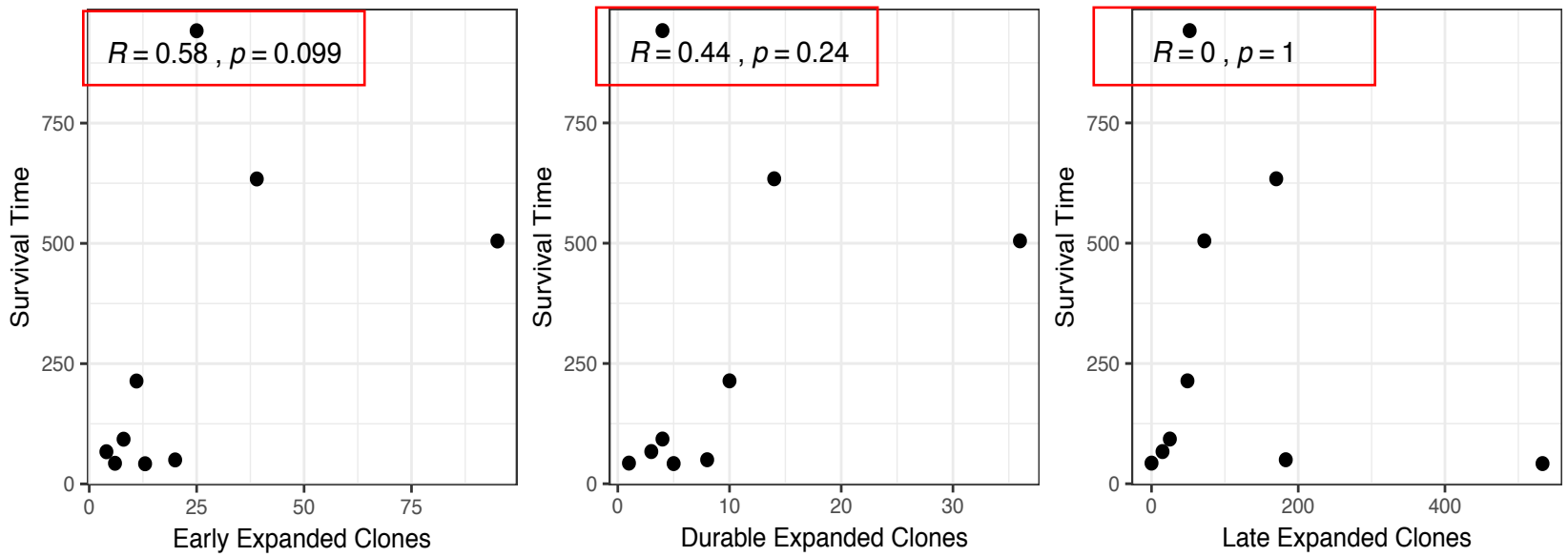
Patients with a clinical response or longer survival: Higher Peripheral Clonality after one cycle of treatment
(at cycle 2, day 1)



Long term survivors: > 6 months
Short term survivors: < 6 months

Early Expanded Clones Most Strongly Correlate With Survival Time (Pre-Pembrolizumab)





Spearman Rho Correlations

- Both high numbers of early and durable clone are associated with longer overall survival times
- The strongest correlation is seen with the number of early expanded clones
- Early vs. late clonal expansion may be influenced by the type of response of the virus is eliciting

Summary & Next Steps

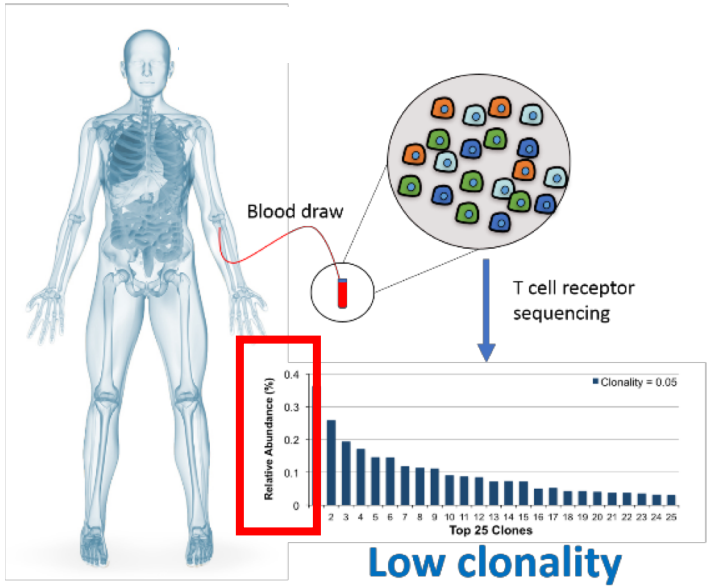
Patients classified as

- “Long term survivors” have higher levels of T cell clonality
- “Short term survivors” have lower levels of T cell clonality

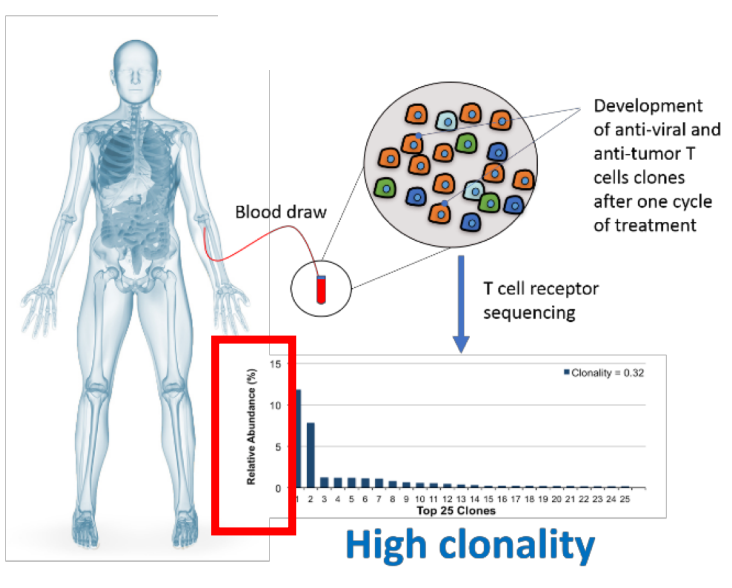
in peripheral blood after one cycle of treatment

All the observations of this initial study will be validated in randomized P2 studies in BC and GI cancer

Non-Responders

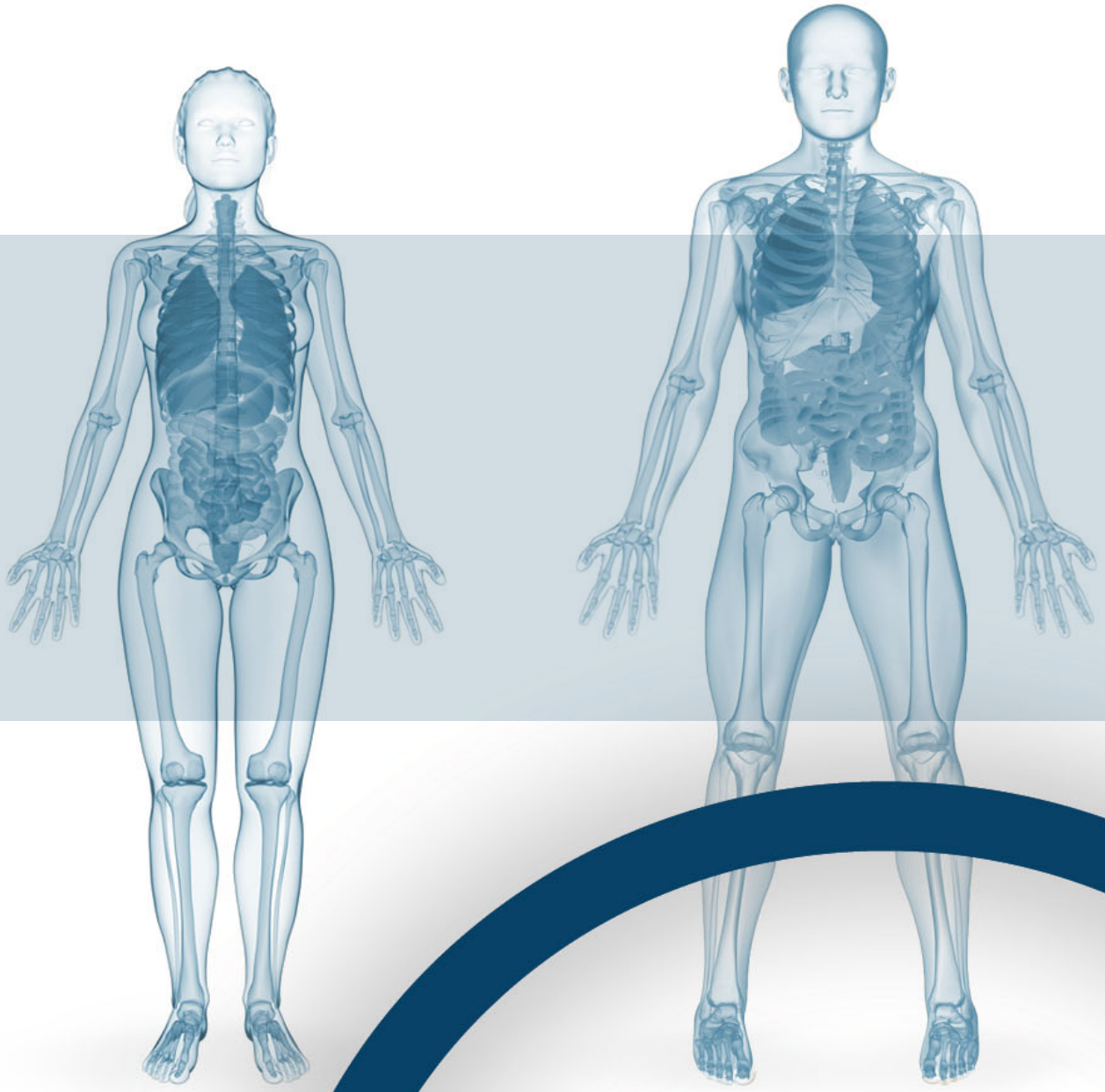


Responders



A study by Hopkins et al. has also shown that on-treatment peripheral T cell clonality associates with survival in MAP pts treated with nivolumab and a pancreatic cancer vaccine (Hopkins, A.C., et al. JCI Insight, 2018. **3**(13)).

Impact of Biomarkers on Clinical & Business Development



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Innately Adaptive™

Influence on Oncolytics' Clinical Development Program

WHY

Increase the number of patients that can be safely and successfully treated with an immunotherapy combination

Overcome resistance of current checkpoint indication

Potentially offer a chemo – limiting/free treatment approach

HOW

Include a prospective biomarker program in our clinical studies

Work closely with academia (thought leaders) and FDA

Prospectively collect biomarker and correlate them with overall response rate

WHAT

For metastatic breast cancer optimize our registration study – Identify patients that derive the best benefit from the treatment

Expand in multiple indications

Pelareorep Clinical Studies

Programs	Indication	Preclinical	Phase 1	Phase 2	Phase 3
Breast Cancer					
pelareorep + combination	mBC				
pelareorep + TECENTRIQ atezolizumab	Early BC	Window of opportunity study			
Gastro-Intestinal Cancer					
pelareorep + KEYTRUDA (pembrolizumab) Injection 100 mg	Pancreatic Cancer				
Multiple Myeloma					
pelareorep + KEYTRUDA (pembrolizumab) Injection 100 mg	R/R MM				
pelareorep + OPDIVO (nivolumab)	R/R MM				

Biomarker Impact on Business Development

FASTER

Quicker time to trial readout

BETTER

Potential to de-risk trial investment via higher probability of trial clinical success

CHEAPER

Trials make for more palatable investment opportunities

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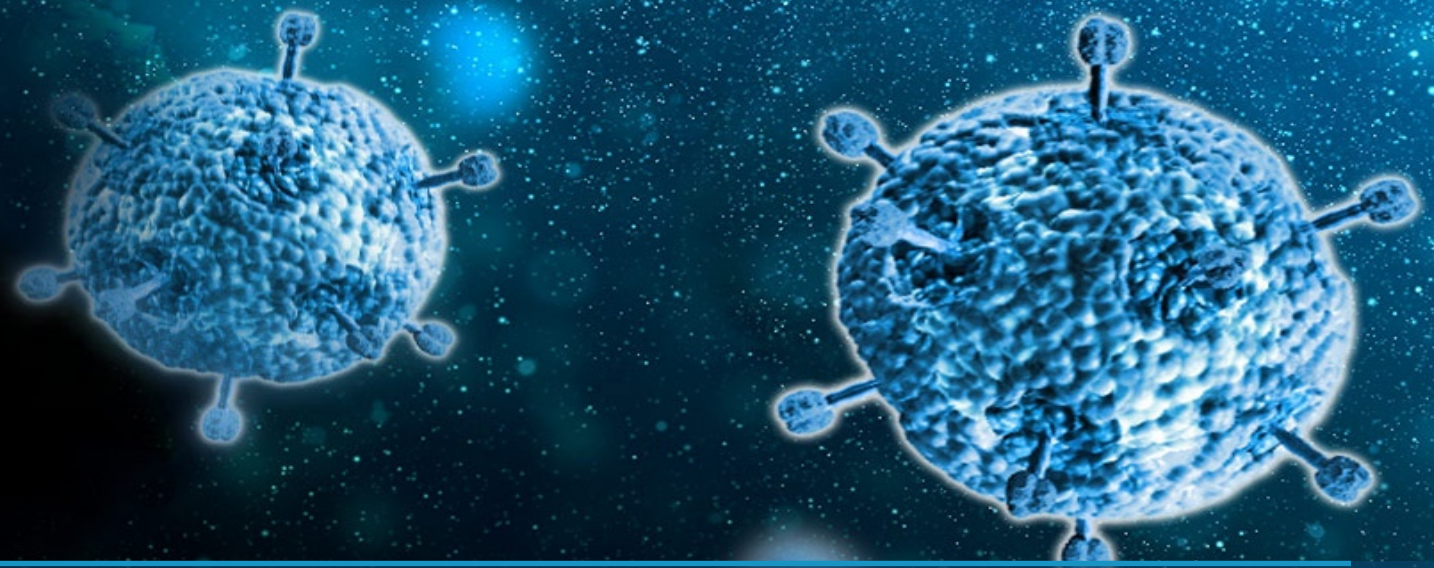
Thanks for your time



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