2023 ASCO® ANNUAL MEETING

BRACELET-1 (PrE0113) – Inducing an inflammatory phenotype in metastatic HR+/HER2- breast cancer with the oncolytic reovirus pelareorep in combination with paclitaxel and avelumab

Amy S Clark, Fengmin Zhao, Paula Klein, Alberto J Montero, Carla Falkson, Elisa-Krill Jackson, Kendrith Rowland, Sagar Sardesai, Jason Incorvati, Patrick Dillon, Antonio C Wolff, Houra Loghmani, Richard Trauger, Thomas Charles Heineman, Matthew C. Coffey, Kathy D Miller

Abstract 1012

PrECOG

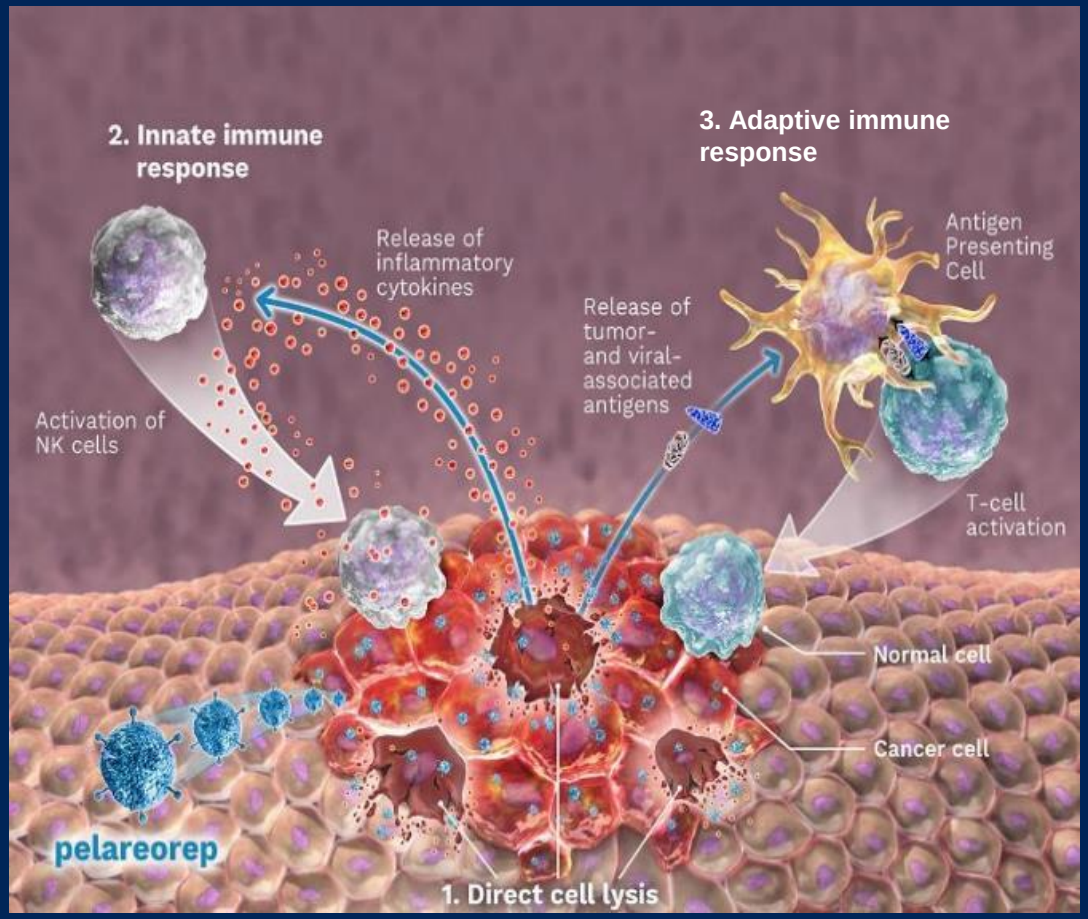
Background
HR+/HER2- Breast Cancer

- Most common phenotype in the early and metastatic setting
- Hormone therapy is the mainstay of treatment
  - CDKi, mTOR, PI3K inhibitors extend hormone benefit
- Chemotherapy initiated at time of hormone resistance
  - No clear optimal sequence
- Indolent course with low tumor mutational burden (TMB)
  - Immune therapy with checkpoint inhibitors has had little role

Background
Oncolytic Reovirus

- Pelareorep is a type 3 reovirus
- Invades and lyses tumor cells[1] and promotes inflammatory tumor microenvironment (TME)
  - Innate immune response: natural killer cell activation[2]
  - Adaptive immune responses: presentation of tumor and viral antigens[2,3]

Image https://www.oncolyticsbiotech.com/technology



1. *Levy JA et al. Nature 220(5167). 1968.*
2. *Errington F et al. J Immunol 180(9). 2008.*
3. *Gujar SA et al. Mol Cancer Ther. 9(11). 2010.*

Background
Pelareorep (PEL)

- Synergistic *in vitro* when combined with taxanes[1,2]
- Randomized phase II trial
  - Longer overall survival (OS) with PEL + paclitaxel (PTX) (10.4 vs. 17.4 mos., HR = 0.65, p = 0.1)[3]
- PTX and PEL cause tumor upregulation of PD-L1 *in vitro* in breast cancer cell lines[4] and clinical samples[5]

1.Heinemann et all 2011 BMC Cancer, 11: 221
2.Sei Et al 2009. Mol Cancer, 8: 47
3. Bernstein V et al.2018 Breast Cancer Res Treat 167(2)
4..Zhang, P et. Al 2008. Mol immunol, 45.
5. Loghmani H et al. 2022 SABCS

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- PTX and PEL cause tumor upregulation of PD-L1 *in vitro* in breast cancer cell lines[4] and clinical samples[5]
- **Could addition of anti-PD-L1 therapy improve the response rate to PTX + PEL therapy?**

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Hypotheses and Aims

Hypotheses

- PEL will induce an inflammatory TME, enhancing the efficacy of PTX in patients with HR+/HER2- MBC
- The addition of anti-PD-L1 antibody avelumab (AVE) to PEL and PTX will be synergistic and improve efficacy

Aims

- To assess safety and estimate efficacy
  - PTX + PEL
  - PTX + PEL + AVE
- To explore changes in peripheral T cell clones in each cohort

BRACELET-1 Study Evaluates Pelareorep-based Combination Therapies in HR+/HER2- Breast Cancer

3 patient safety run-in for Cohort 3 then treatment groups randomized 1:1:1

Advanced or metastatic HR+/HER2- breast cancer (N = 48)

R

Cohort 1 (n=15): Paclitaxel (PTX)

Treatment cycle (28 days)
Paclitaxel administration: Days 1, 8, 15

Cohort 2 (n=15): Paclitaxel + pelareorep (PTX + PEL)

Treatment Cycle (28 days)
Paclitaxel administration: Days 1, 8, 15
Pelareorep administration: Days 1, 2; 8, 9; 15, 16

Cohort 3 (n=15): Paclitaxel + pelareorep + avelumab (PTX + PEL + AVE)

Treatment Cycle (28 days)
Paclitaxel administration: Days 1, 8, 15
Pelareorep administration: Days 1, 2; 8, 9; 15, 16
Avelumab administration: Days 3, 17

Primary Endpoint

- ORR at week 16

Secondary Endpoints

- ORR at end of study
- OS, PFS
- Safety and tolerability
- Biomarker assessments including
  - PD-L1 expression
  - T cell clonality

ORR = Objective response rate
PFS = Progression-free survival
OS = overall survival

Statistical Methods

- N=48, 3 patients for safety run-in of the triplet then 15 patients per cohort
- Sample size was based on practical considerations to allow for assessment of safety, tolerability, and preliminary biological and clinical activity
- Power calculation was not performed, and formal tests of statistical significance were not planned
- With 15 patients per arm, the 80% confidence interval for the difference in ORR between treatment arms will have half-width of about 28%. The expected differences between PTX vs PTX + PEL (about 25% difference) and PTX vs PTX + PEL + AVE (about 50% difference).

Key Eligibility

- Estrogen receptor (ER) and/or progesterone receptor (PR) positive as defined by ≥ 1% tumor cell nuclei immunoreactive
- HER2 negative (ASCO-CAP) - Equivocal disease allowed
- Progressed on at least 1 hormone-based therapy with a CDK4/6 inhibitor
- No prior chemotherapy for metastatic disease
- ECOG PS 0-1
- Measurable disease by RECIST V1.1
- Adequate organ and hematologic function

Disposition

- 48 patients were enrolled between June 2020 and June 2022
  - Three patients from PTX withdrew consent prior to starting therapy
- Two patients- early discontinuation (1 week):
  - PTX + PEL
  - PTX + PEL + AVE
  - Considered non-responders and censored for PFS
- Nine patients (9/33, 27%) discontinued PEL and six patients (6/17, 35%) discontinued AVE due to toxicity

Patient Characteristics

	PTX	PTX + PEL	PTX + PEL + AVE	Total
No. of patients	15	16	17	48
Median Age (range)	60 (46-74)	52.5 (38-71)	59 (37-70)	55.5 (37-74)
Race				
White	12 (80%)	12 (75%)	13 (76%)	37 (77%)
Black	1 (7%)	3 (19%)	4 (24%)	8 (17%)
Asian	2 (13%)	1 (6%)	0	3 (6%)
Ethnicity				
Hispanic	1 (7%)	3 (19%)	1 (6%)	5 (10%)
Non-Hispanic	14 (93%)	13 (81%)	16 (94%)	43 (90%)
Postmenopausal	12 (80%)	8 (50%)	10 (59%)	30 (62%)
ECOG PS				
0	10 (67%)	11 (69%)	10 (59%)	31 (65%)
1	5 (33%)	5 (31%)	7 (41%)	17 (35%)

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Disease Characteristics and Prior Therapy

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No. of patients	15	16	17	48
Visceral disease	12 (80%)	13 (81%)	15 (88%)	40 (83%)
Prior Therapy				
Taxane (neo/adjuvant)	6 (40%)	4 (25%)	5 (29%)	15 (31%)
Alpelisib	1 (7%)	1 (6%)	1 (6%)	3 (6%)
Everolimus	2 (13%)	1 (6%)	2 (12%)	5 (10%)
CDK4/6 inhibitor	15 (100%)	16 (100%)	17 (100%)	48 (100%)

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Primary Endpoint: Response at 16 Weeks

Response[1,2]	PTX (n=15)	PTX + PEL (n=16)	PTX + PEL + AVE (n=14)
CR	0	0	0
PR	3	5	2
SD	4	5	7
PD	4	1	4
[3]Unevaluable	0	1	0
[4]Not assessed	4	4	1
ORR at week 16	3 (20%) (95% CI: 4%, 48%)	5 (31%) (95% CI: 11%, 59%)	2 (14%) (95% CI: 2%, 43%)
Disease control (CR+PR+SD)	7 (47%) (95% CI: 21%, 73%)	10 (62%) (95% CI: 35%, 85%)	9 (64%) (95%CI: 35%, 87%)

[1]Only the 45 randomized patients were included in the response analysis
[2]Response based on RECIST V1.1 investigator assessment
[3]Patients unevaluable were considered non-responders
[4]Patients not assessed did not undergo 16 week disease assessment and were considered non-responders

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Progression-Free Survival*

	PTX	PTX + PEL	PTX + PEL + AVE
N[1]/PFS events[2]	15/8	16/8	14/9
6 Month PFS	62% (95% CI: 28%, 84%)	86% (95% CI: 54%, 96%)	50% (95% CI: 18%, 74%)
Median PFS (months)	6.4 (95% CI: 2.0, NR)	9.6 (95% CI: 6.5, NR)	5.8 (95% CI: 3.5, NR)

[1]Only the 45 randomized patients were included in the analysis
[2]Five patients had missing response data at the data cutoff date and were censored at randomization for PFS
NR- not reached

*Summary calculation based on cutoff date May 2023

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Adverse Events (AE): All Grades[1,2]

[Fifteen most common reported as attributed to study drug(s)]

Grade	PTX (N=12)		PTX + PEL (N=16)		PTX + PEL + AVE (N=17)	
	Any	≥ 3	Any	≥ 3	Any	≥ 3
Alopecia	6 (50%)	-	9 (56%)	-	8 (47%)	-
Anemia	7 (58%)	-	5 (31%)	-	10 (59%)	1 (6%)
Anorexia	4 (33%)	-	5 (31%)	-	5 (29%)	-
Chills	-	-	7 (44%)	-	5 (29%)	-
Diarrhea	1 (8%)	-	6 (38%)	1 (6%)	8 (47%)	2 (12%)
Fatigue	5 (42%)	-	12 (75%)	2 (12%)	8 (47%)	1 (6%)
Infusion related reaction	1 (8%)	-	3 (19%)	-	9 (53%)	1 (6%)
Leucopenia	2 (17%)	-	3 (19%)	1 (6%)	11 (65%)	5 (29%)
LFT[3] Abnormality	3 (25%)	-	6 (38%)	2 (12%)	9 (53%)	2 (12%)
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PRESENTED BY: Amy S. Clark, MD MSCE

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Adverse Event of Special Interest:
Viral-Like Symptoms More Common with Pelareorep

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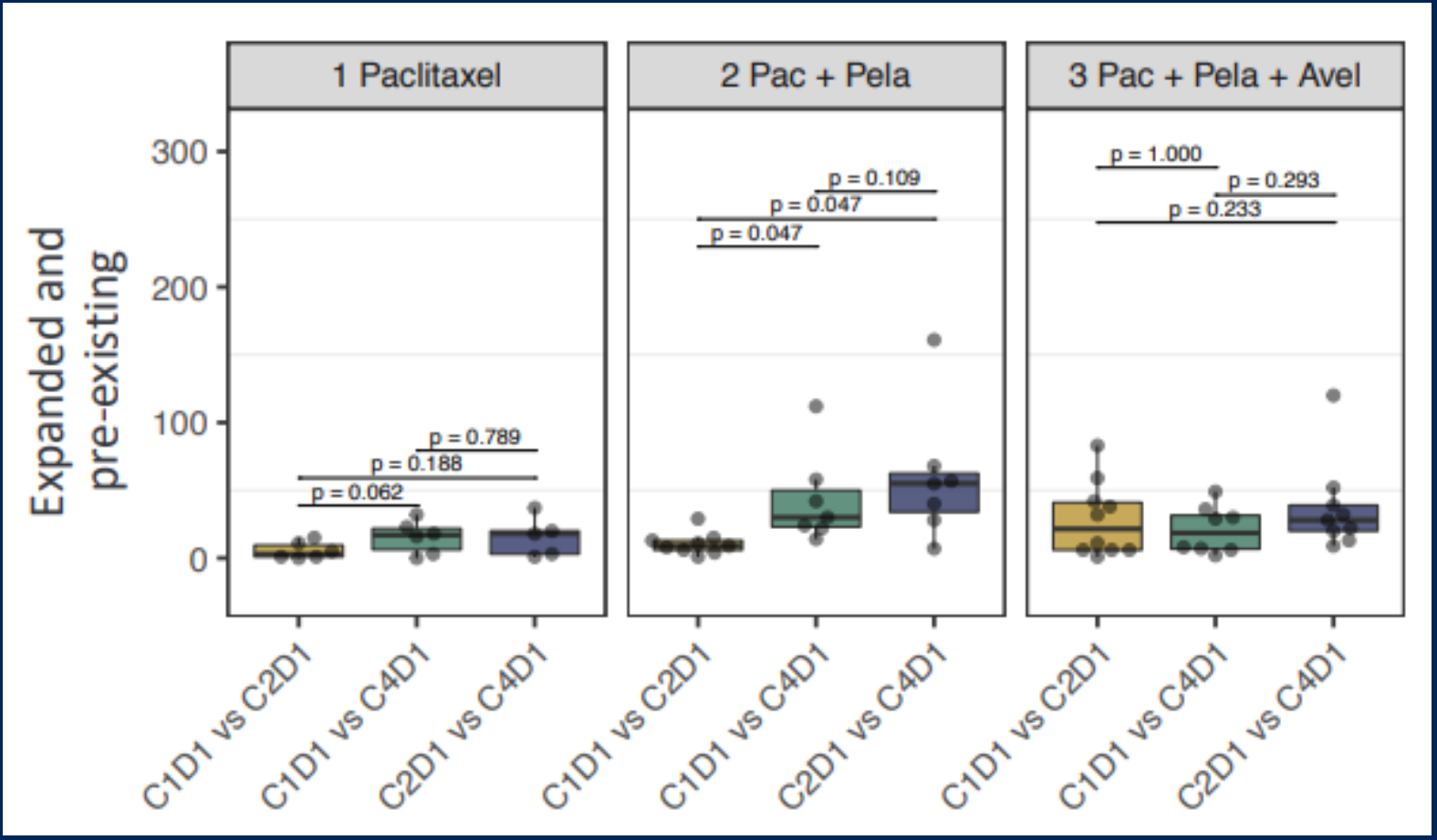
Chills	-	7 (44%)	5 (29%)
Pyrexia	-	8 (50%)	11 (65%)
Influenza-like illness	-	4 (25%)	5 (29%)
Infusion related reaction	1 (8%)	3 (19%)	9 (53%)

- Over one-third of patients who received PEL had fever, chills and/or influenza-like symptoms
- Infusion reactions more common in patients who received PEL or PEL and AVE

Expansion of Pre-Existing T Cell Clones Greatest in PTX + PEL Cohort



- ImmunoSEQ Assay
- Pairwise comparisons between visits were made using Wilcox test
- Significant expansion of T cell clones seen by Cycle 4 Day 1 in PTX + PEL but not PTX + PEL+ AVE

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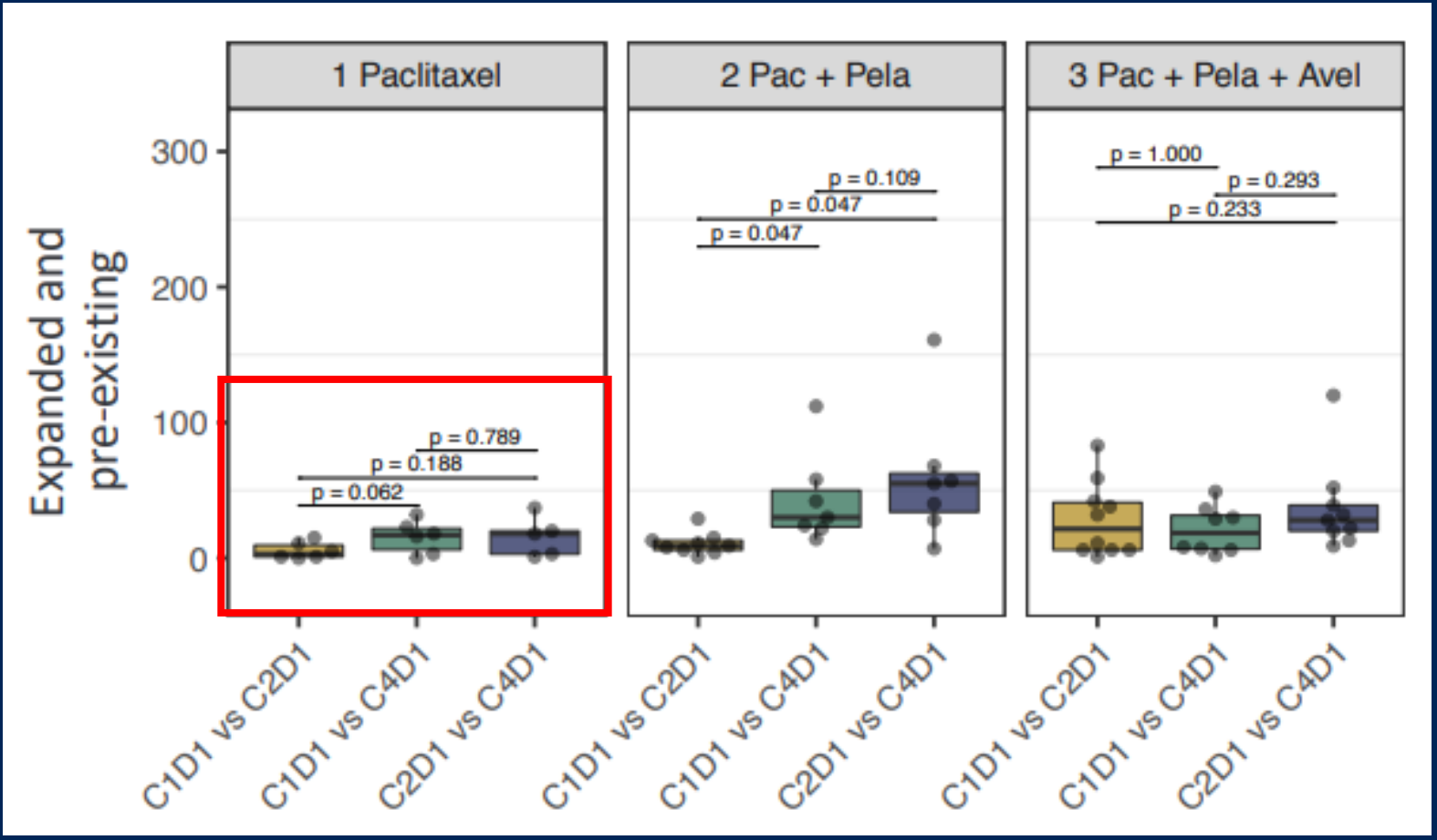

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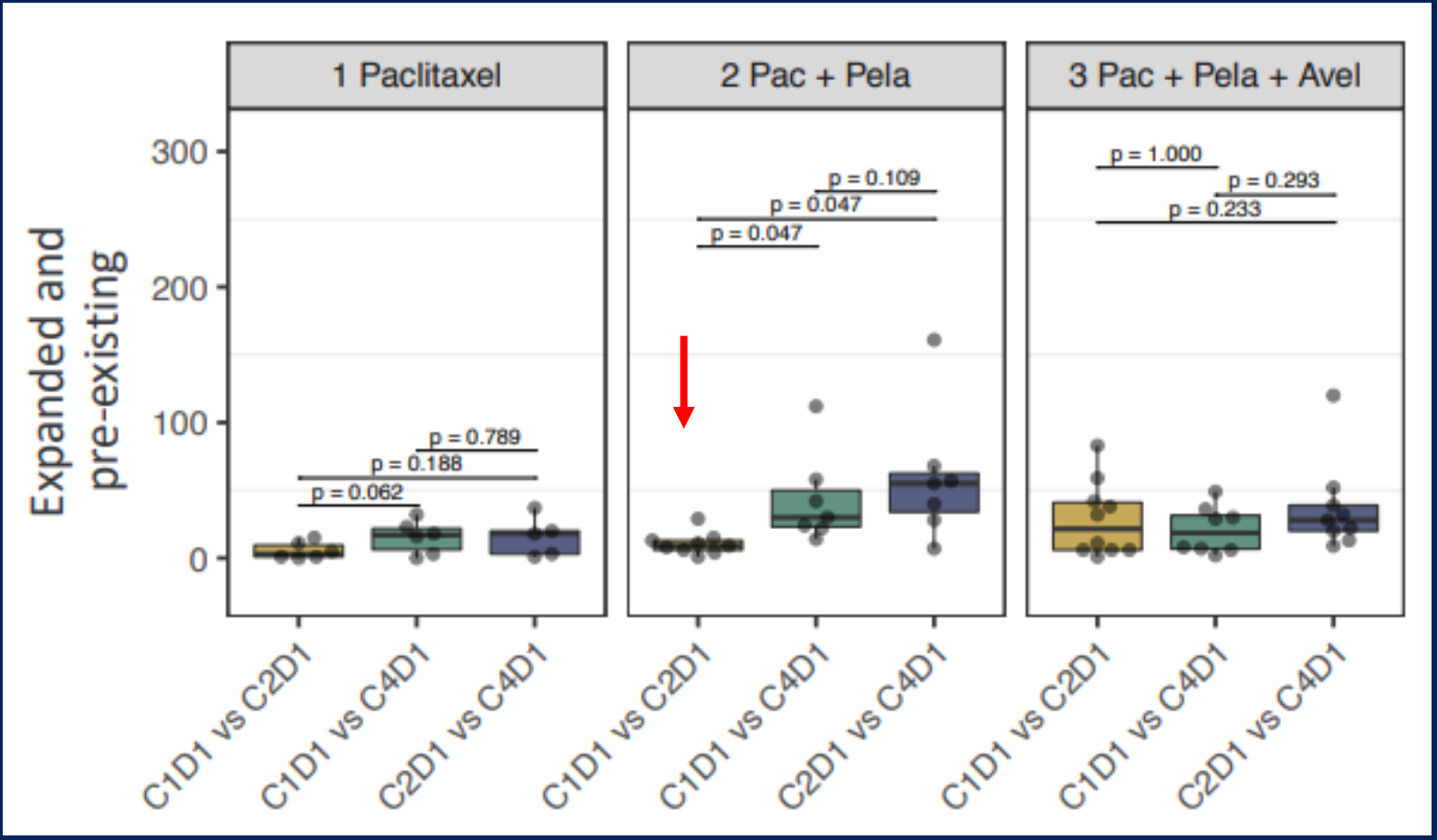

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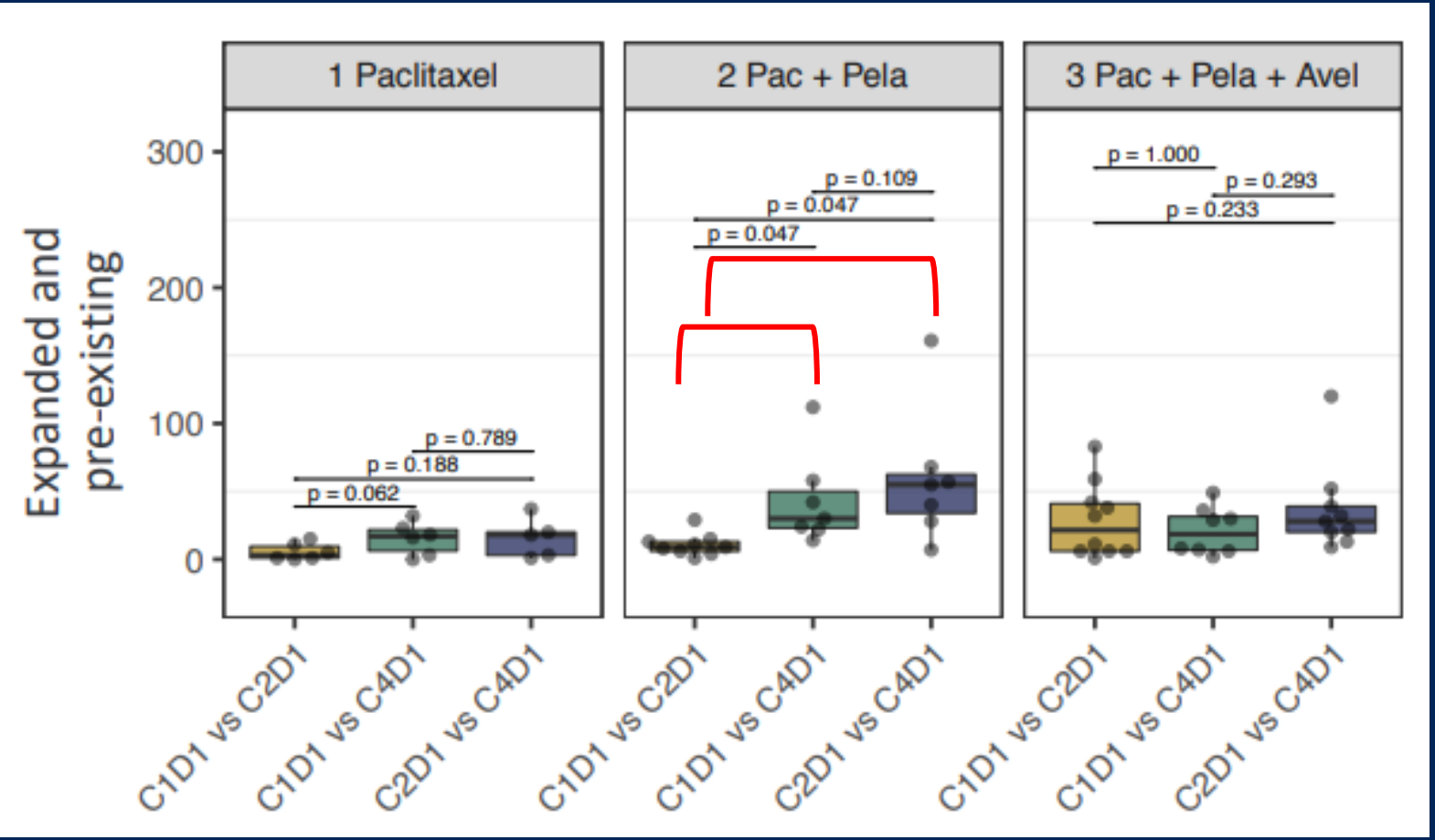

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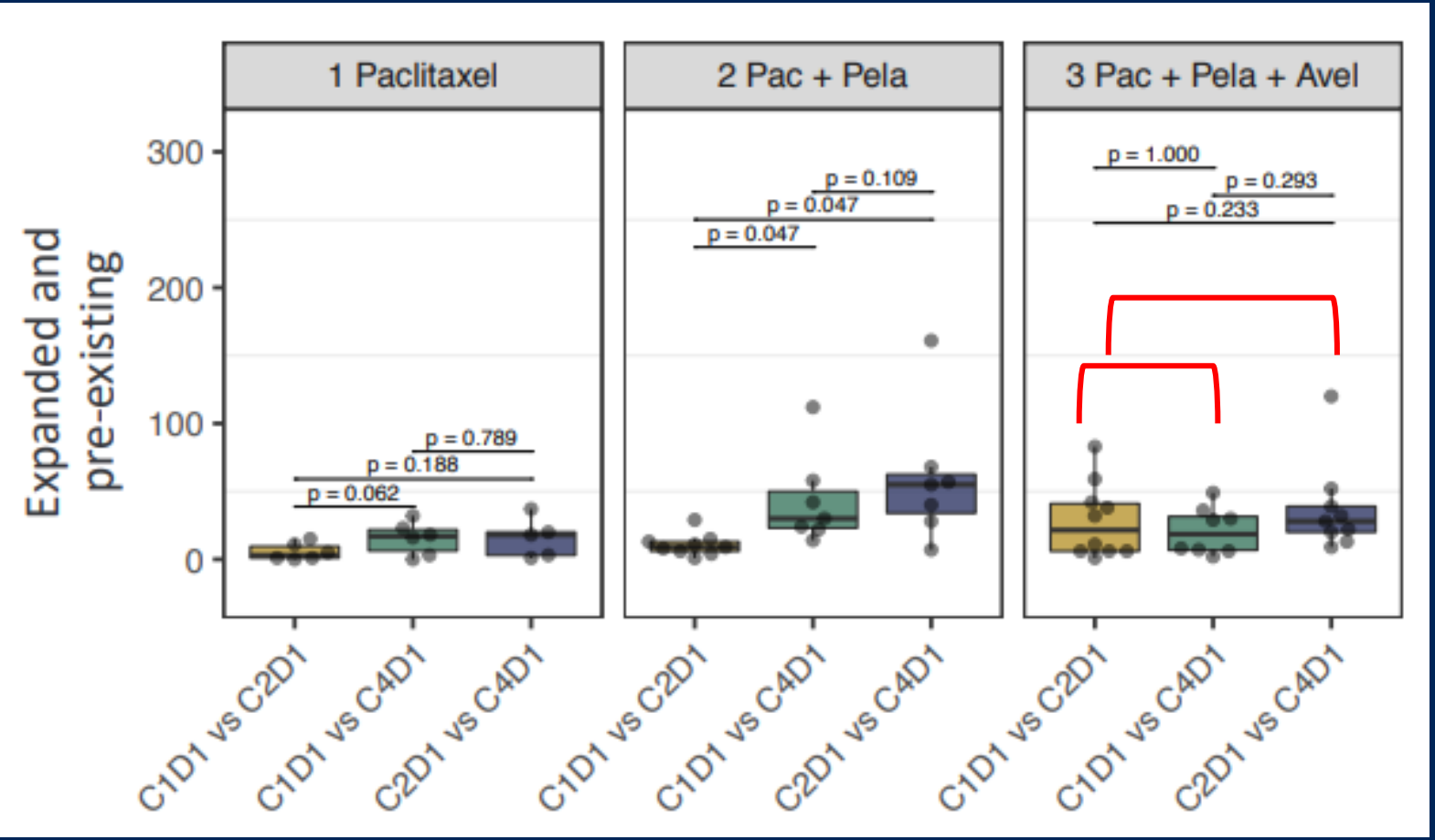

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Conclusions

- The addition of PEL to PTX is worthy of further study
  - 32% 16 week ORR
  - 86% 6-month PFS
  - Addition of AVE increased toxicity, no obvious increase in efficacy
- Flu-like viral reactions are common with PEL
  - 27% of patients receiving PEL discontinued due to toxicity
  - Attentive and proactive supportive care necessary
- PEL alters T-cell subsets
  - AVE blunts PEL-induced increase in T-cell subsets
  - Further biomarker analyses are underway
- Overall survival data continue to mature

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- All patients and their caregivers
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Indiana University
Mt Sinai School of Medicine
Ochsner Clinic Foundation
Ohio State University
Thomas Jefferson University
University Hospitals Cleveland Medical Center
University of Miami
University of Pennsylvania
University of Rochester
University of Virginia
Rutgers Cancer Institute of New Jersey
Washington University
West Virginia University

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