

IMMUNOCORE

PRAME Phase 1 study of brenetafusp (IMC- F106C) in cutaneous melanoma

May 31, 2024



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Agenda



Welcome

Bahija Jallal, CEO



Insights from KIMMTRAK

David Berman, Head of R&D



Phase 1/2 study of brenetafusp targeting PRAME

Dr. Diwakar Davar, UPMC

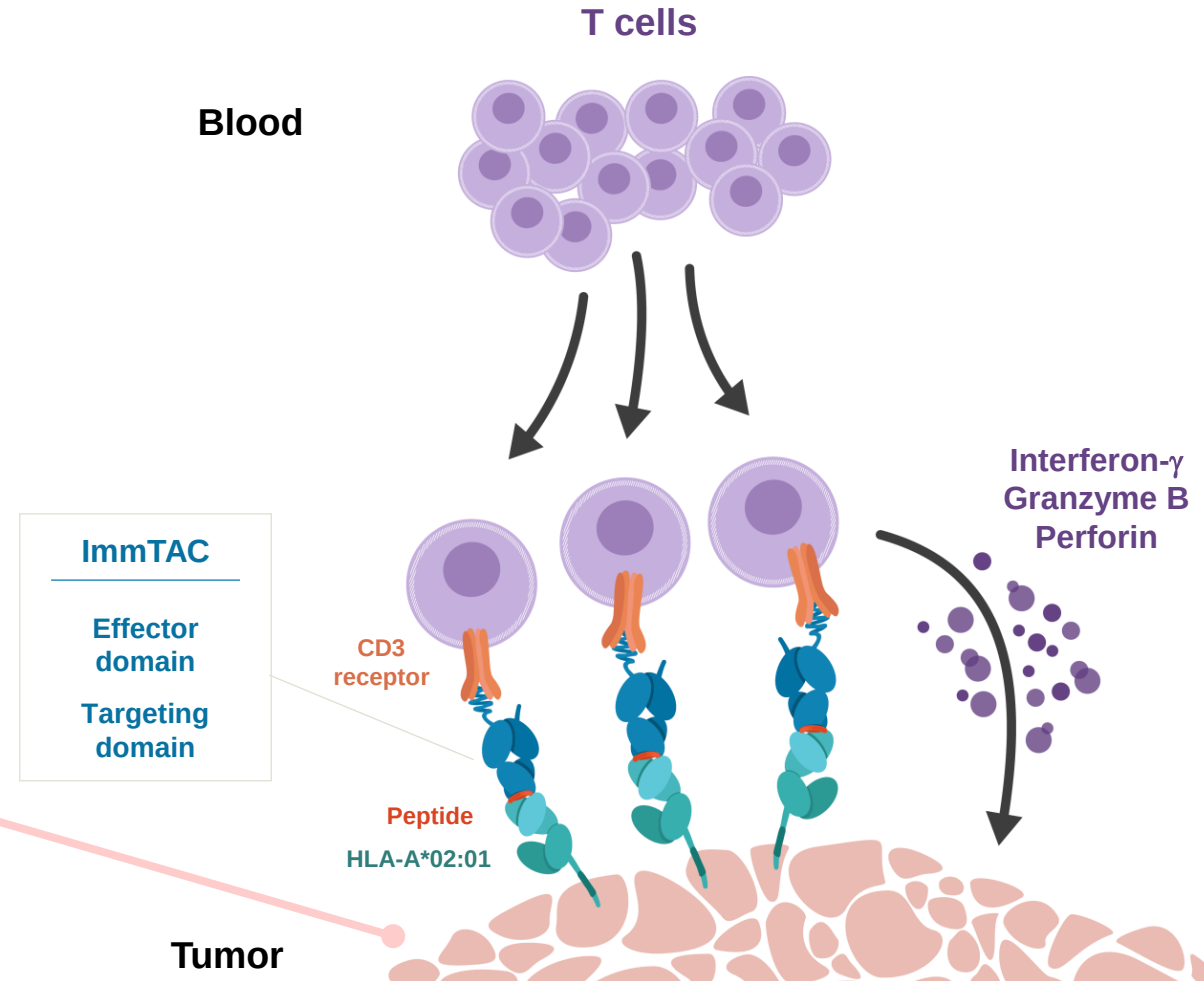
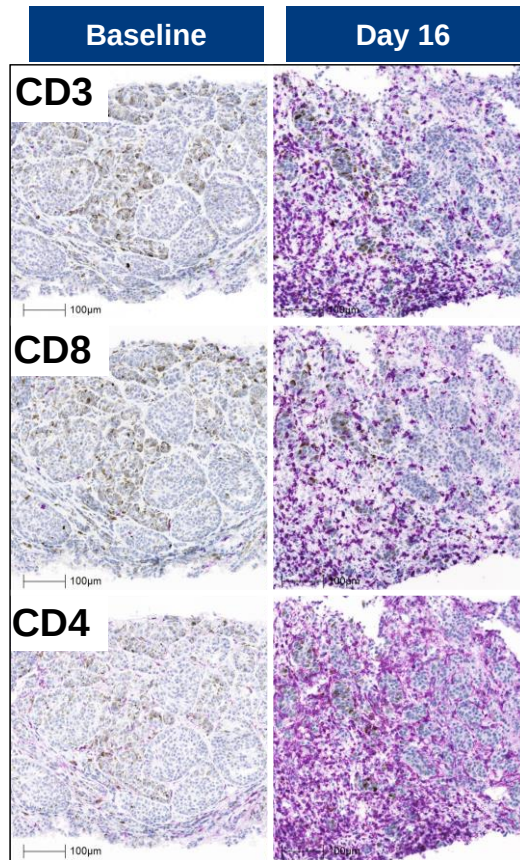
Q&A Session

Pioneering a new class of immunotherapy



KIMMTRAK: OS and PFS benefit with unique mechanism of action

T cell infiltration into tumors



In pre-clinical studies...

→ **Distinct mechanism of action than checkpoints**

In tumor biopsies...

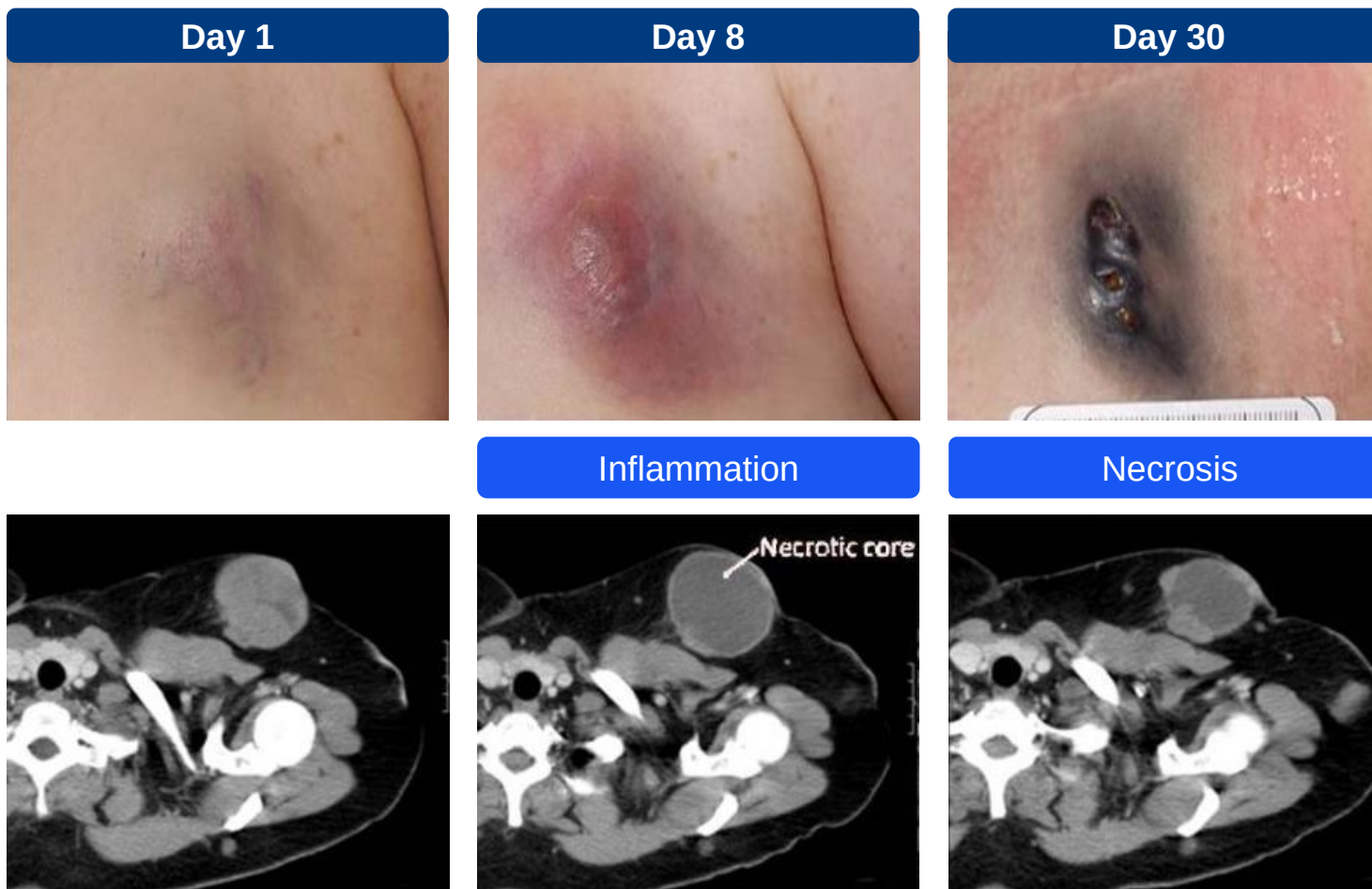
→ **More robust T cell infiltration and activation than checkpoints¹**

In Phase 1-3...

→ **Measuring full clinical benefit different than checkpoints**

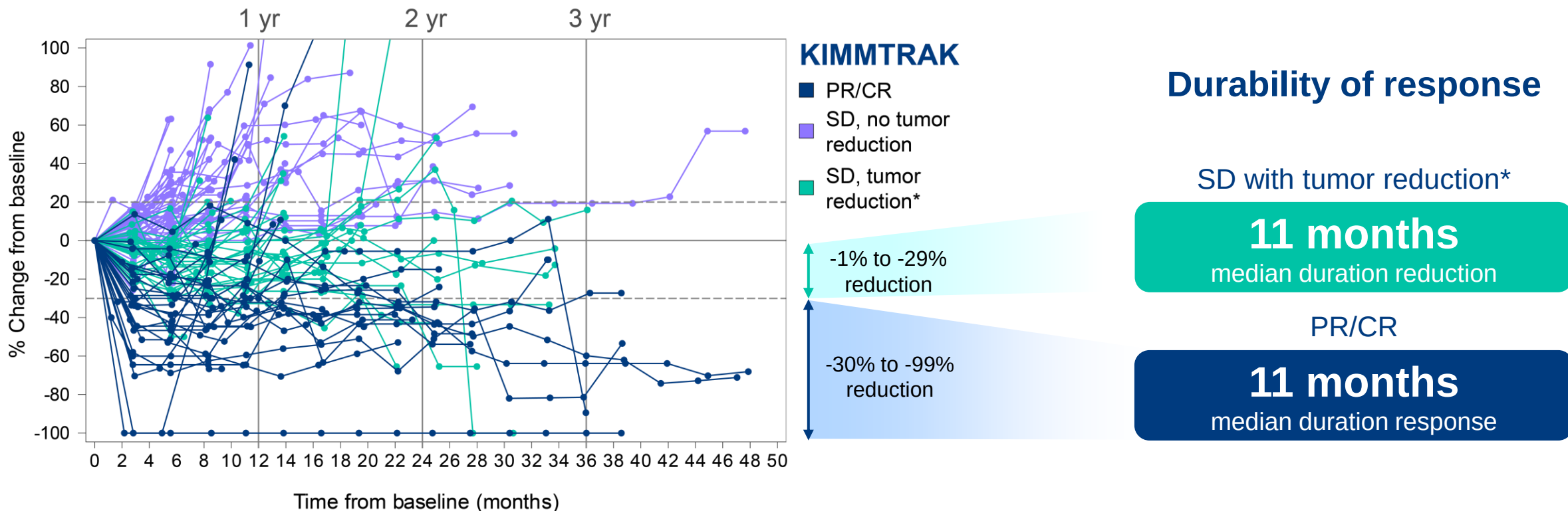
Case Study: clinical benefit in patient with SD and tumor reduction (-7%) due to necrosis and inflammation

Cutaneous melanoma patient¹ KIMMTRAK monotherapy Ph 1



Definition of KIMMTRAK benefit broader than RECIST ORR

24% patients (**11% PR + 13% SD** with confirmed tumor reduction)- durable with **median 11 mo.**



SD patients with tumor reduction have same durability as PR (both 11 months)

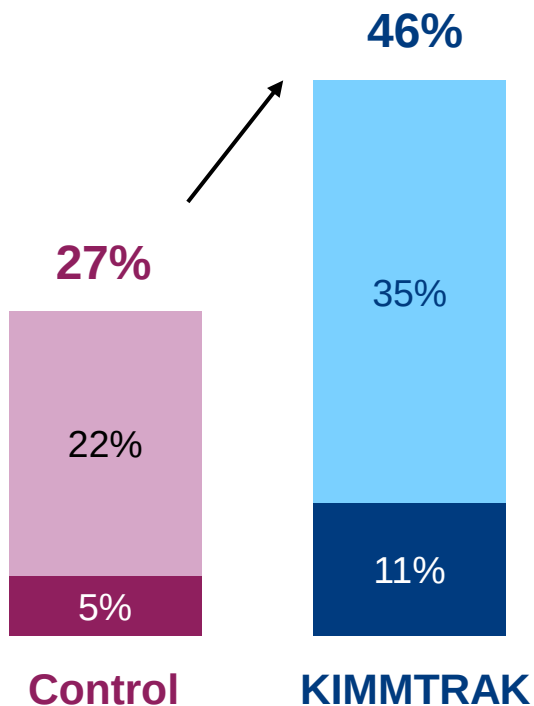
Similar observation in 2L+ mUM, ASCO 2024 poster #9529

Disease control rate, strong predictor of significant PFS

DCR mostly of stable disease (SD)

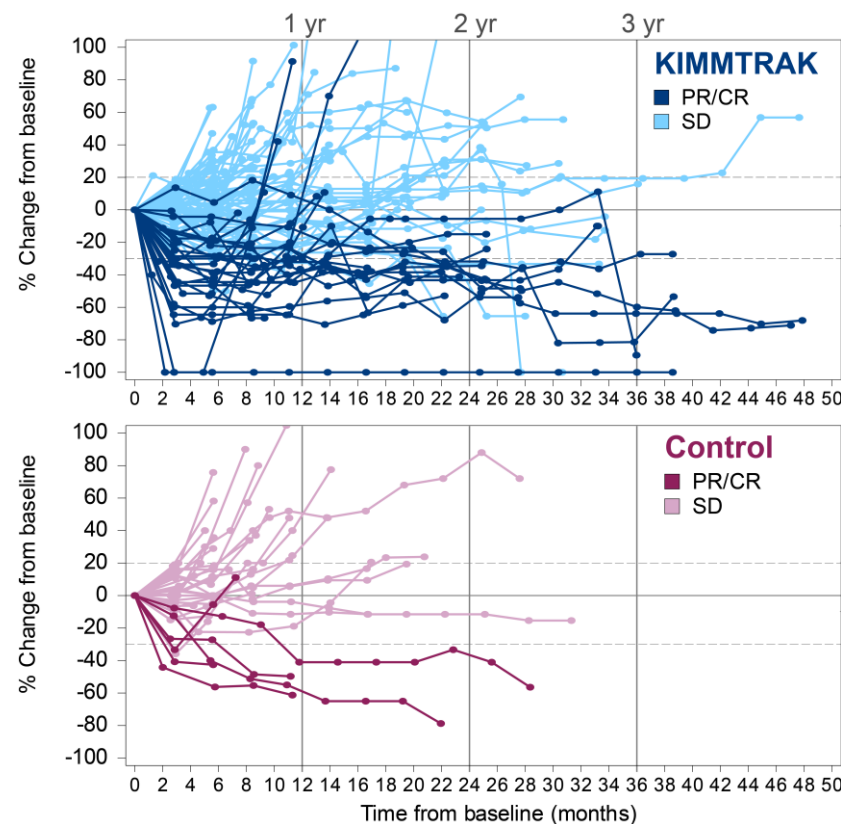
Disease control rate

SD
PR/CR



Both PR and SD **very durable**

Drives **PFS benefit**



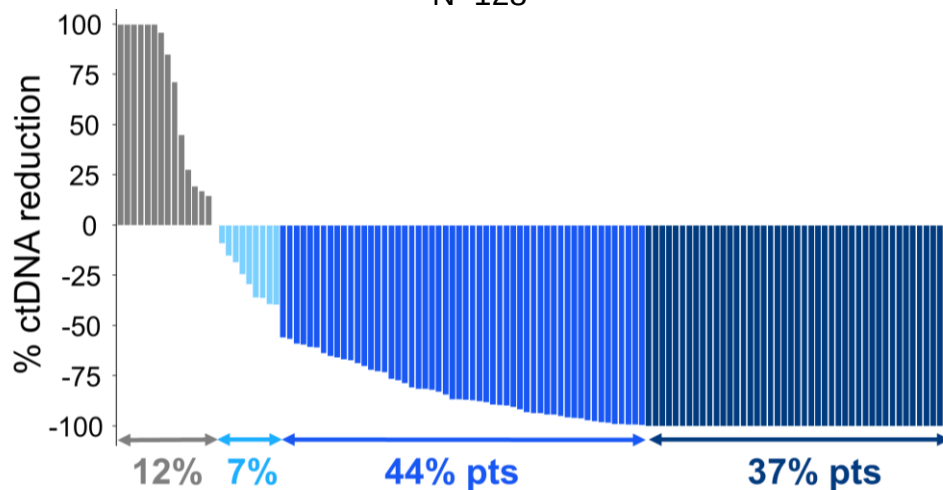
**PFS
HR 0.73**

OS (HR 0.51) best endpoint to capture all benefit

KIMMTRAK activity higher in early lines of therapy vs 2L+

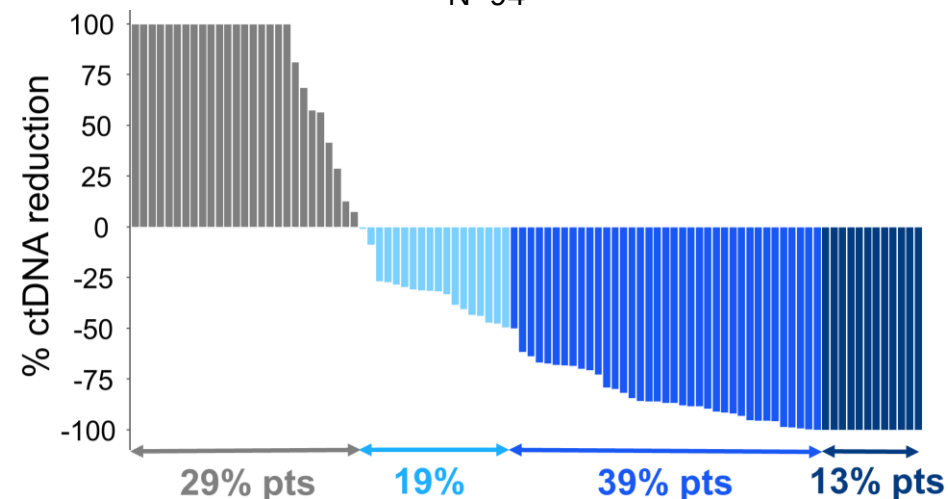
1L KIMMTRAK¹

N=128



2L+ KIMMTRAK²

N=94



Clearance

37%

Molecular response

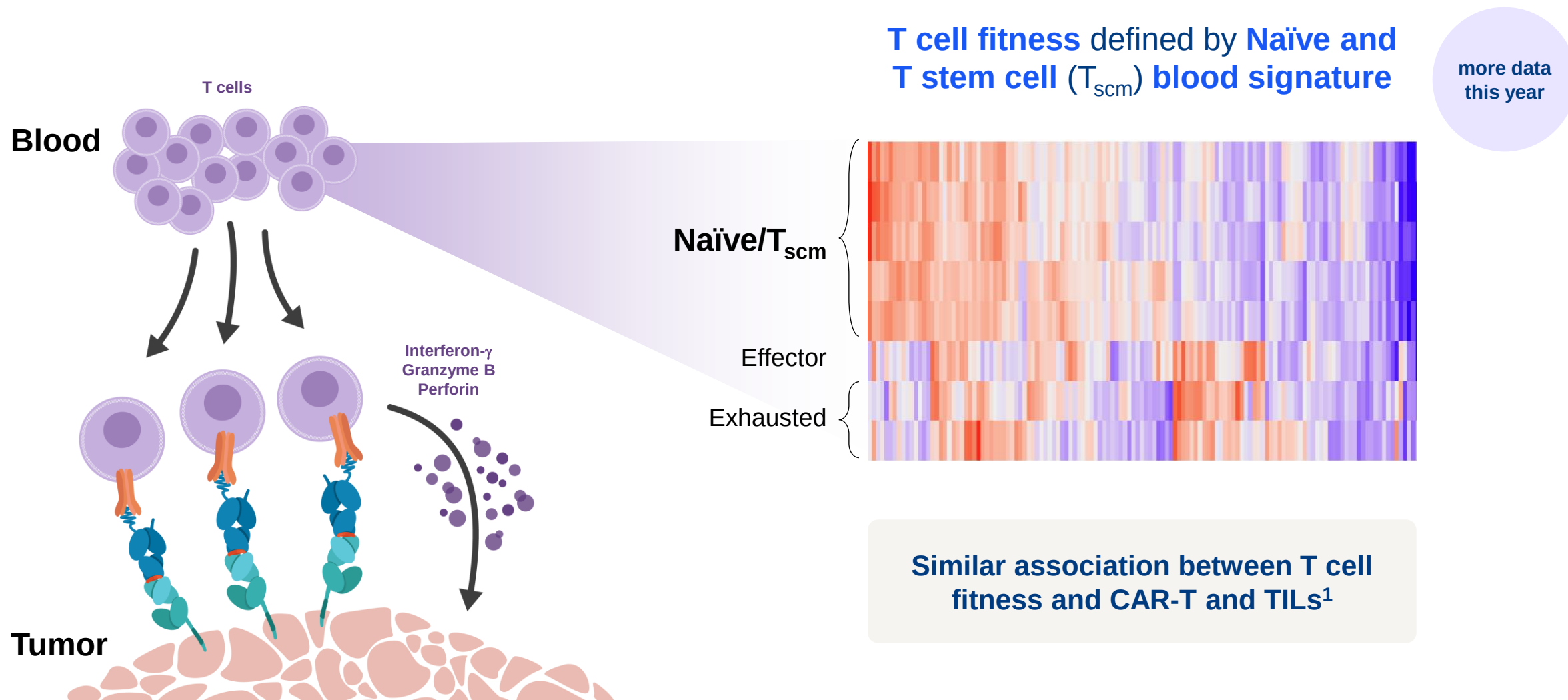
81%

13%

42%

ctDNA reduction is early surrogate of OS benefit and independent of CT/MRI

T cell fitness in blood important parameter of ImmTAC benefit



Insights from KIMMTRAK that can be applied to ImmTAC platform

- **Distinct MoA with more robust T cell infiltration and activation than checkpoints**
 - Distinct measures of benefit required - broader than RECIST ORR
- **Disease control, including durable tumor reduction, is a hallmark of platform**
 - High DCR provides confidence for PFS in Phase 3
- **ImmTAC activity higher in early lines of therapy vs 2L+**
 - Endogenous T cell fitness in blood important parameter of activity

Diwakar Davar, MD, MS

Clinical Director of the Melanoma and Skin Cancer Program, University of Pittsburgh Medical Center (UPMC) Hillman

- **Board-certified in internal medicine and medical oncology and completed both his residency and fellowship at UPMC**
- **Clinical interests include management of advanced melanoma and the development of early phase studies to test novel immunotherapeutic approaches individually and in combination in patients with advanced cancer**
- **Oversees the melanoma and skin cancer clinical trials portfolio at UPMC**



Phase 1 safety and efficacy of brenetafusp (IMC-F106C), a PRAME × CD3 ImmTAC bispecific, in post-checkpoint cutaneous melanoma (CM)

Omid Hamid¹, Anja Williams², Juanita Lopez³, Daniel Olson⁴, Takami Sato⁵, Heather Shaw⁶, Claire F. Friedman⁷, Fiona Thistlethwaite⁸, Mark R. Middleton⁹, Celeste Lebbe¹⁰, Vincent T. Ma¹¹, Benjamin Izar¹², Peter Lau¹³, Oliver Bechter¹⁴, Peter Kirk¹⁵, Yuan Yuan¹⁶, Shannon Marshall¹⁶, and Diwakar Davar¹⁷

¹The Angeles Clinical and Research Institute, a Cedars-Sinai Affiliate, Los Angeles, CA; ²Sarah Cannon Research Institute, London, United Kingdom; ³The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust, Sutton, United Kingdom; ⁴University of Chicago, Comprehensive Cancer Center, Chicago, IL; ⁵Sidney Kimmel Cancer Center, Jefferson University, Philadelphia, PA; ⁶University College London Hospital, London, United Kingdom; ⁷Memorial Sloan Kettering Cancer Center, New York, NY; ⁸The Christie NHS Foundation and University of Manchester, Manchester, United Kingdom; ⁹Medical Sciences Division, University of Oxford, Headington, Oxford, United Kingdom; ¹⁰Université Paris Cité, Dermatolo-Oncology AP-HP Hôpital Saint-Louis, INSERM U976, Paris, France; ¹¹University of Wisconsin Carbone Cancer Center, Madison, WI; ¹²Columbia University Medical Center, New York, NY; ¹³Linear Clinical Research, Harry Perkins Institute for Medical Research, Nedlands, WA, Australia; ¹⁴UZ Gasthuisberg - Katholieke University Leuven, Leuven, Belgium; ¹⁵Immunocore, Abingdon, United Kingdom; ¹⁶Immunocore, Rockville, MD; ¹⁷University of Pittsburgh Medical Center, Hillman Cancer Center, Pittsburgh, PA

Disclosures

Consulting: ACM Bio, Ascendis, Castle, Clinical Care Options (CCO), Gerson Lehrman Group (GLG), Immunitas, Medical Learning Group (MLG), Replimmune, Trisalus, Xilio Therapeutics;

Contracted Research for Institution: Arcus, Immunocore, Merck, Regeneron Pharmaceuticals Inc., Tesaro/GSK;

Royalties: None.

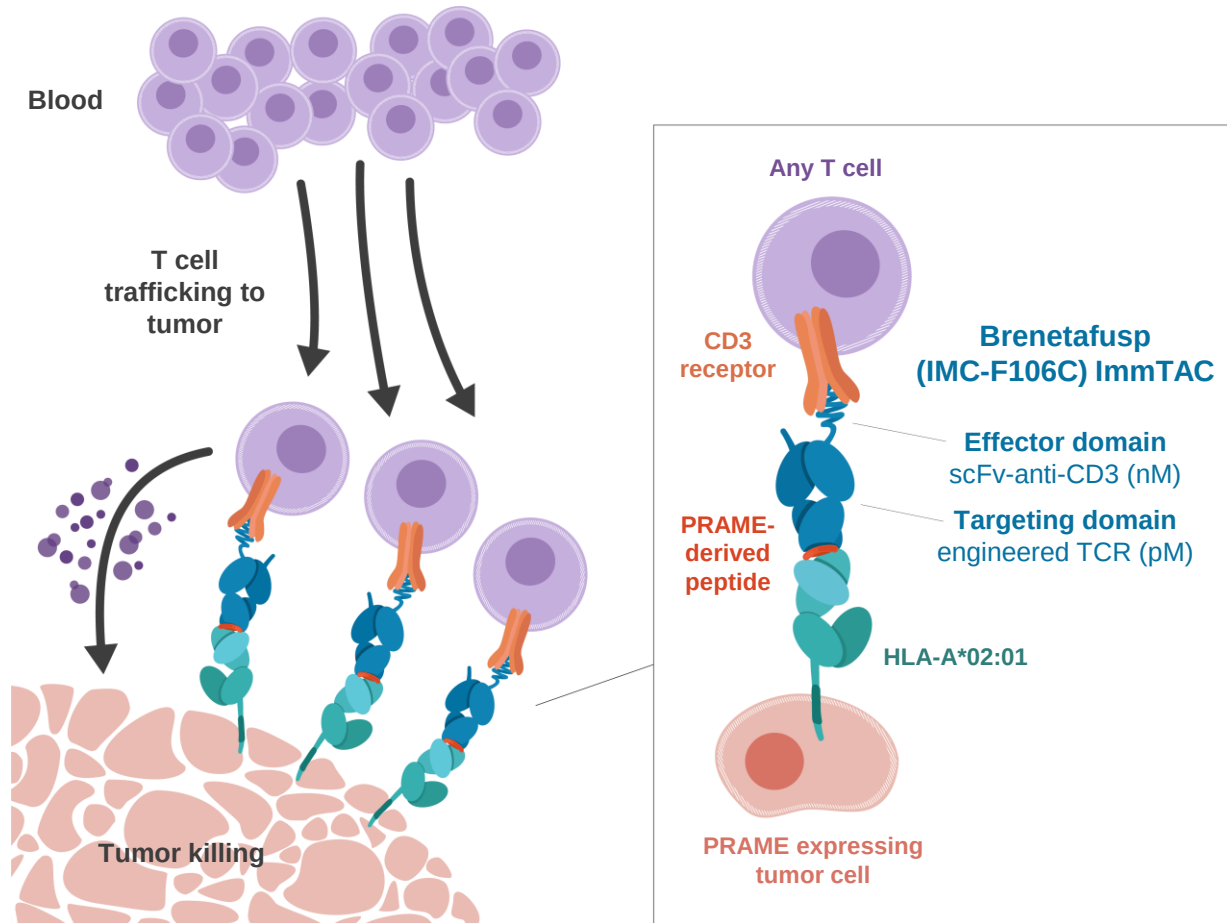
Speaker: Castle Biosciences.

Stock: Zola

Disclaimer

All statements contained in this presentation are based on preclinical and clinical trial data related to an investigational molecule, IMC-F106C. Development of this molecule is ongoing and, therefore, statements relating to study data to date should not be regarded as definitive reflections of safety, efficacy or the risk-benefit profile of the molecule.

Brenetafusp: ImmTAC bispecific T cell engager targeting HLA-A2-presented peptide from PRAME



- TCR bispecific ImmTAC molecules redirect polyclonal T cells to target cancer cells by recognizing intra-/extra-cellular cancer proteins
- ImmTAC platform validated by tebentafusp (gp100 × CD3) with OS (HR 0.51) and PFS benefit (HR 0.73) in mUM²
- ImmTAC tolerability with immune checkpoints demonstrated with tebentafusp in cutaneous melanoma²
- PRAME is broadly expressed in several tumor types, including ~90% cutaneous melanoma (CM), with minimal normal tissue expression¹

ImmTAC, Immune mobilizing T cell receptor Against Cancer; mUM, metastatic uveal melanoma; OS, overall survival; TCR, T cell receptor

1. Internal IHC data analysis and TCGA; Kaczorowski, *et al.* 2022 Am J Surg Pathol 2022; 46(11):1467-1476

2. Nathan P, *et al.* N Engl J Med 2021;385:1196-206; Hamid O, *et al.* J Immunother Cancer 2023;11(6):e006747

Brenetafusp Phase 1/2 Study Design

Key objectives:

Primary

- Safety
- MTD/expansion dose
- Efficacy (in expansion only)

Additional

- Pharmacokinetics
- Molecular response (ctDNA)
- Predictive biomarkers

Key eligibility criteria for CM:

- Unresectable or metastatic
- HLA-A*02:01 (central testing)
- Previously treated with
 - immune checkpoint inhibitors
 - BRAFi/MEKi, if applicable

Weekly IV infusion

1-2 step doses

Target dose

RECIST tumor assessment every 9 weeks
ctDNA assessment every 3 weeks

- Previously presented Ph1 data¹
 - Identified target doses ≥ 20 mcg as consistently pharmacodynamically and clinically active
 - Included 7 efficacy-evaluable CM pts
- Tumor PRAME expression evaluated by IHC
- Gene expression in whole blood at baseline evaluated by bulk RNASeq

IV, intravenous; MTD, maximum tolerated dose; 1. Hamid O, *et al.* Ann Oncol 2022; 33 Suppl 7: S875

* 47 monotherapy patients at brenetafusp target dose of ≥ 20 mcg including 40 new patients and follow-up on 7 CM patients previously presented

Dose escalation

Brenetafusp
monotherapy

Pembrolizumab
combination

Chemotherapy
combinations

Other
combinations

Expansion

Cutaneous
melanoma

Ovarian

NSCLC

Endometrial

Results
from
N=47*

Initial
results from
N=9

EudraCT No. 2019-004046-16; NCT04262466
Data cut-off date: 18-Mar-24

CM Demographics and baseline characteristics

Brenetafusp monotherapy and in combination with pembrolizumab

Characteristic	Monotherapy N=47	+ Pembro N=9
Age, yr – median (range)	64 (31-79)	65 (24-78)
Female – n (%)	19 (40%)	4 (44%)
ECOG status 0 – n (%)	27 (57%)	8 (89%)
Baseline disease status		
Stage III/IV M1a	3 (6%)	3 (33%)
Stage IV M1b/c/d	44 (94%)	6 (67%)
Brain metastasis – n (%)	10 (21%)	2 (22%)
Liver metastasis – n (%)	21 (45%)	3 (33%)
Sum of target lesions*, mm – median (range)	84 (14-309)	73 (24-117)
Prior therapy		
# lines – median (range)	2 (1-9)	4 (1-7)
Anti-PD1	47 (100%)	9 (100%)
Primary resistant† – n (%)	14 (30%)	6 (67%)
Anti-CTLA4	38 (81%)	8 (89%)
BRAF inhibitor	7 (15%)	4 (44%)
PRAME status (IHC)		
Positive‡	42 (89%)	9 (100%)
H-score§ – median	215	155

Patients were heavily pre-treated

- All received prior checkpoint inhibitors (CPI)
 - Median 2 prior anti-PD1 regimens
 - 81% prior ipilimumab – nearly all in combination with nivolumab
 - 38% had another IO, in addition to anti-PD1, anti-CTLA4
- Pembro combo pts. more heavily pre-treated
 - Higher percentage with prior BRAFi and primary resistance to anti-PD1

PRAME expression was high (median H score 215 in monotherapy)†

Includes patients receiving target doses ≥20mcg

* Sum of target lesions at baseline; one pembro combo pt had non-target lesions only

† Primary resistant to anti-PD1: progressed within 6 months of starting first anti-PD1-containing regimen

‡ PRAME positive group for efficacy analysis includes H-score ≥1 and pts with unknown PRAME IHC results; maximum H-score 300

§ Amongst IHC evaluable pts (n=38 mono, n=5 combo)

Brenetafusp monotherapy was well tolerated

TRAE in ≥ 15% of patients (N=47)

Preferred Term (%)	Any grade	Grade 3 / 4
ANY	43 (92%)	19 (40%)
Cytokine release syndrome*	24 (51%)	-
Rash (composite)†	23 (49%)	1 (2%)
Pyrexia	17 (36%)	1 (2%)
Chills	13 (28%)	-
Lymphocyte decrease	12 (26%)	11 (23%)
Pruritus	11 (23%)	-
Nausea	9 (19%)	-
Fatigue	7 (15%)	-

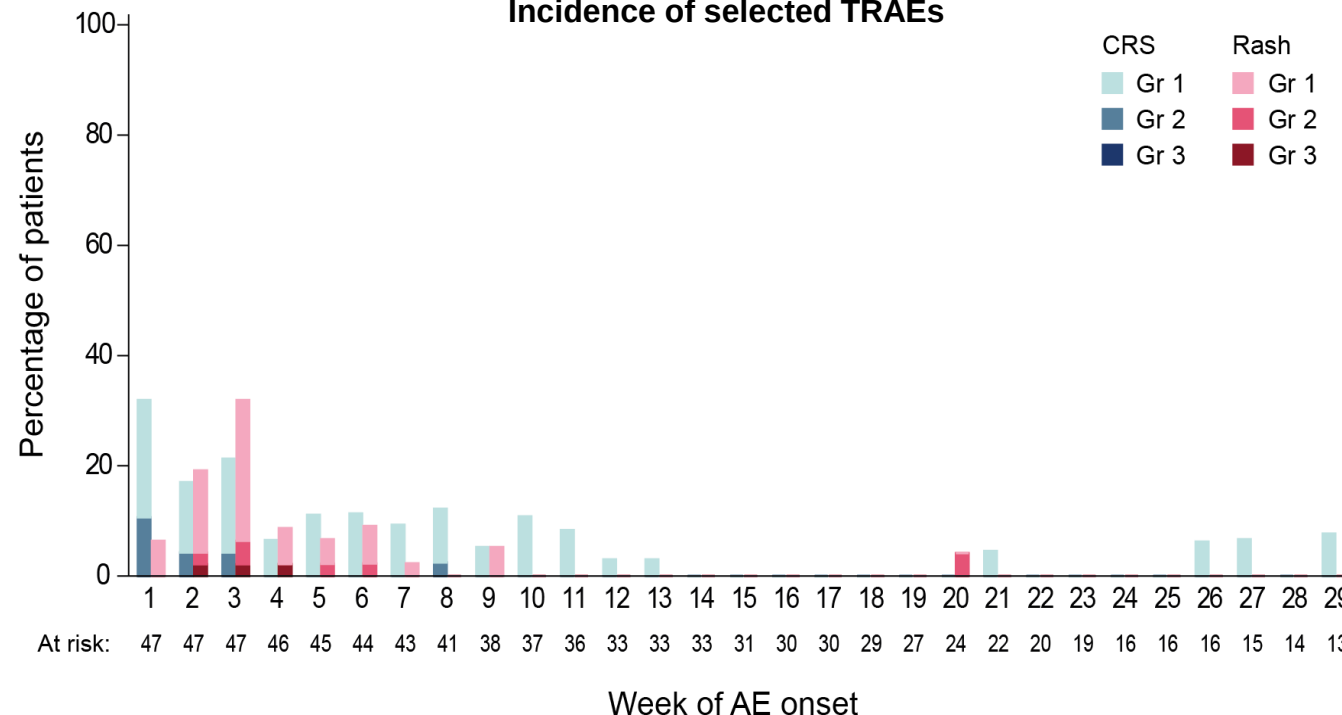
Includes patients receiving target doses ≥20mcg

* CRS graded per ASTCT 2019 criteria; all other AE per CTCAE v5.0

† Rash is a composite term for a list of skin toxicities of any grade (Nathan *et al.* 2021)

Other G3 treatment-related adverse events (TRAE, in 1 pt each): anemia, chronic inflammatory demyelinating polyneuropathy, fever, hypertension, hypotension, hypoxia, pain in extremity, tumor lysis syndrome, urticaria

Incidence of selected TRAEs

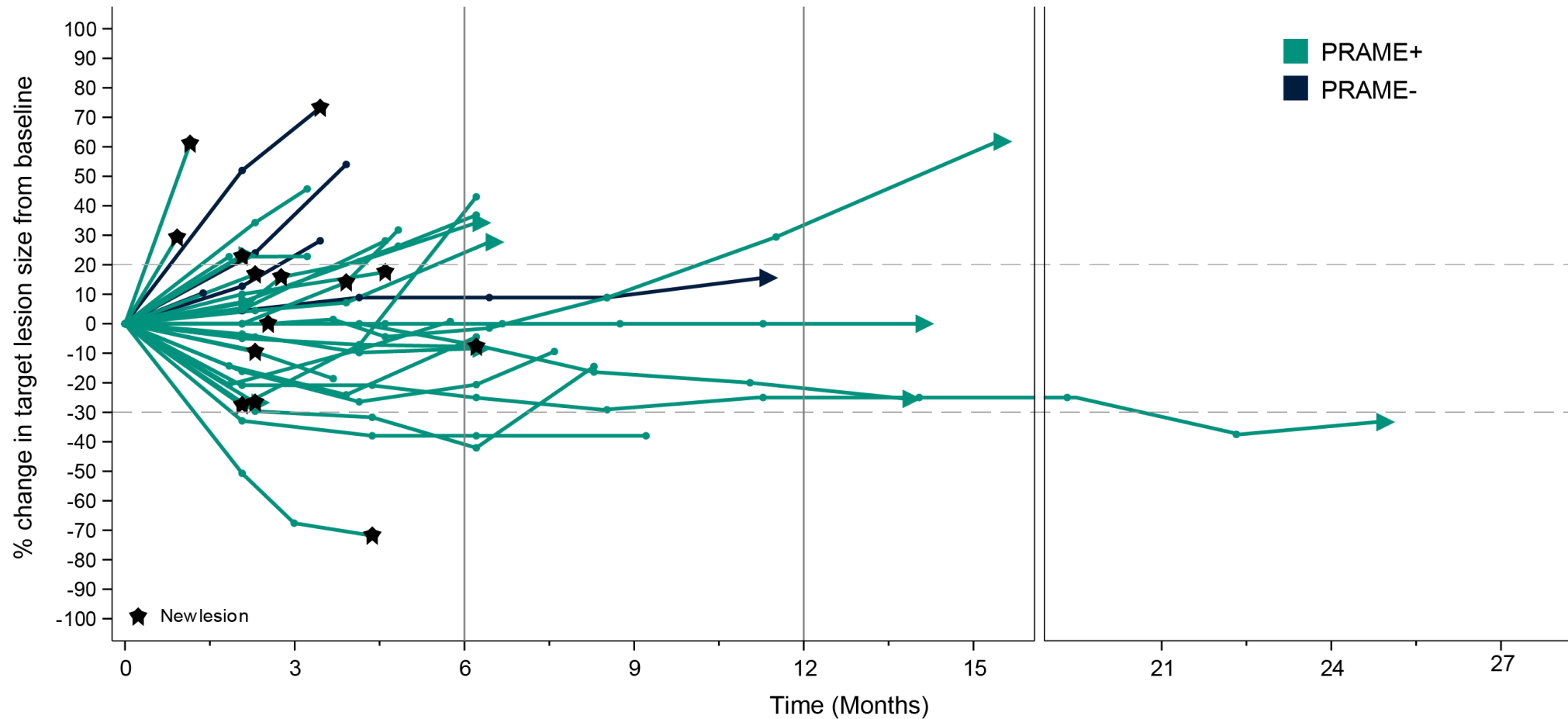


- Safety consistent with previous report; no new signal with continued dosing
- Most frequent TRAE was G1/G2 CRS, consistent with mechanism
- TRAE frequency and severity attenuated over time

- The only G4 TRAEs were lymphocyte decrease (n=11) / lymphopenia (n=3), transient and related to mechanism
- No severe neutropenia observed
- 1 TRAE resulted in treatment discontinuation
- No treatment-related deaths

Clinical benefit characterized by durable disease control

Brenetafusp monotherapy (n= 36 evaluable*)



PRAME positive group for efficacy analysis includes H-score ≥ 1 and pts with unknown PRAME IHC results

* 36/47 patients had baseline and at least one tumor assessment on treatment; 10 patients had no evaluable post-baseline tumor scans and 1 had non-target lesions only at baseline

Clinical benefit characterized by disease control

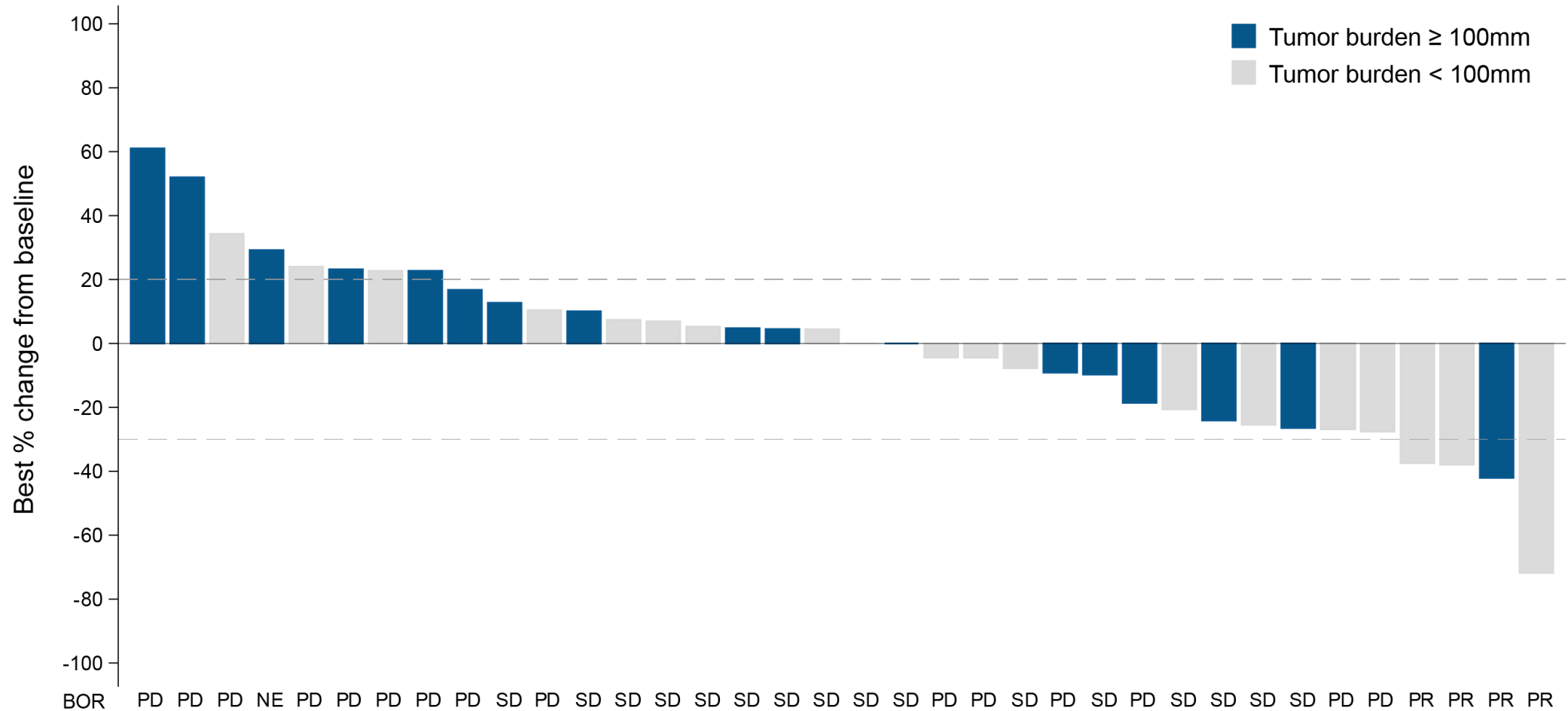
	N	DCR (PR+SD)	PR + SD with confirmed tumor reduction*	ORR
All mono	36	56%	28%	11%
PRAME+	31	58%	32%	13%
PRAME-	5	40%	0%	0%

Reduction in tumor burden is associated with clinical benefit across ImmTAC platform

Nathan NEJM¹; Middleton CCR²; see ASCO 2024 poster #9529

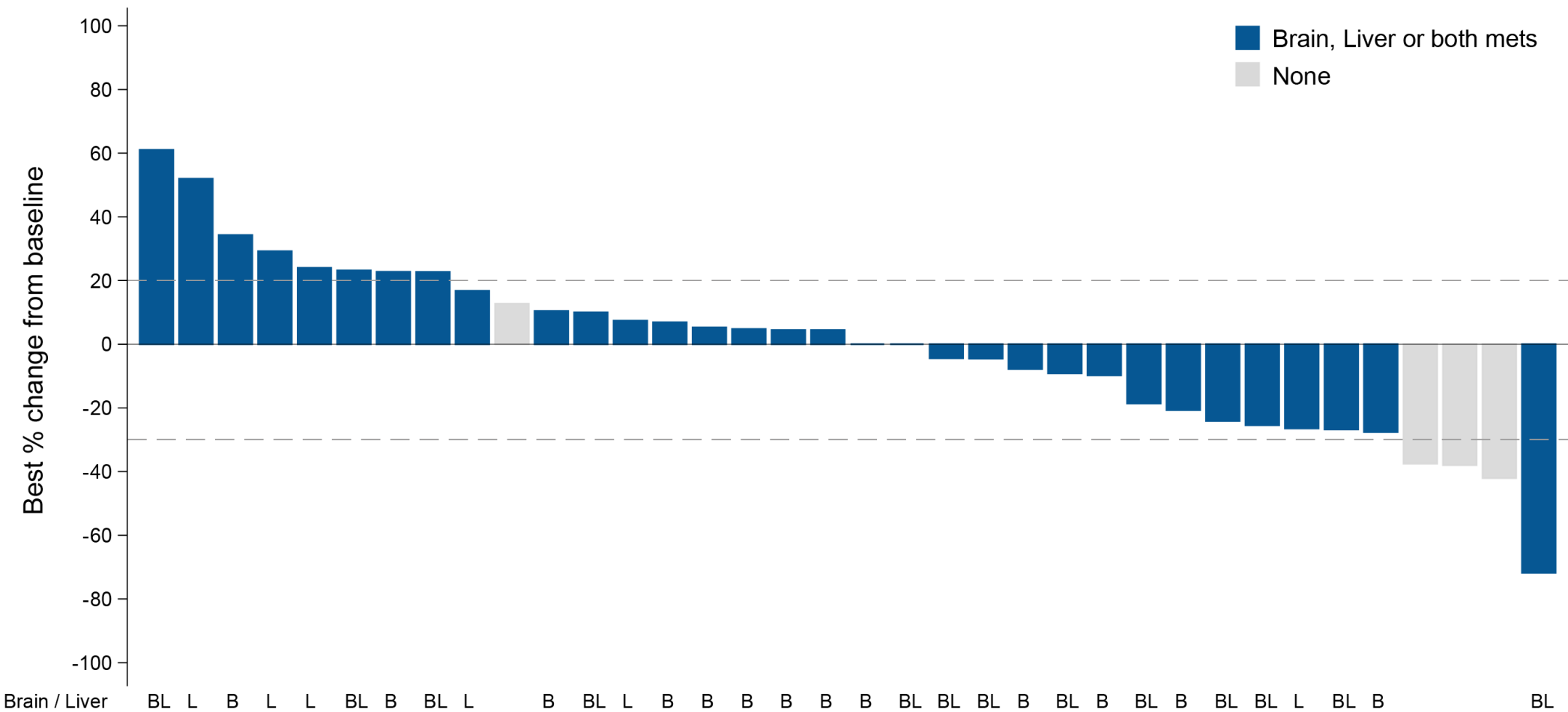
PRAME positive group for efficacy analysis includes H-score ≥1 and pts with unknown PRAME IHC results
*Defined as patients with PR + patients SD or better who have tumor reduction that is confirmed in a subsequent scan after at least 4 weeks with no progressive disease in between
1. Nathan P, *et al.* N Engl J Med 2021;385:1196-206; 2. Middleton M, *et al.* Clin Can Res; 26:5869-5878

Tumor reduction observed in patients with high tumor burden



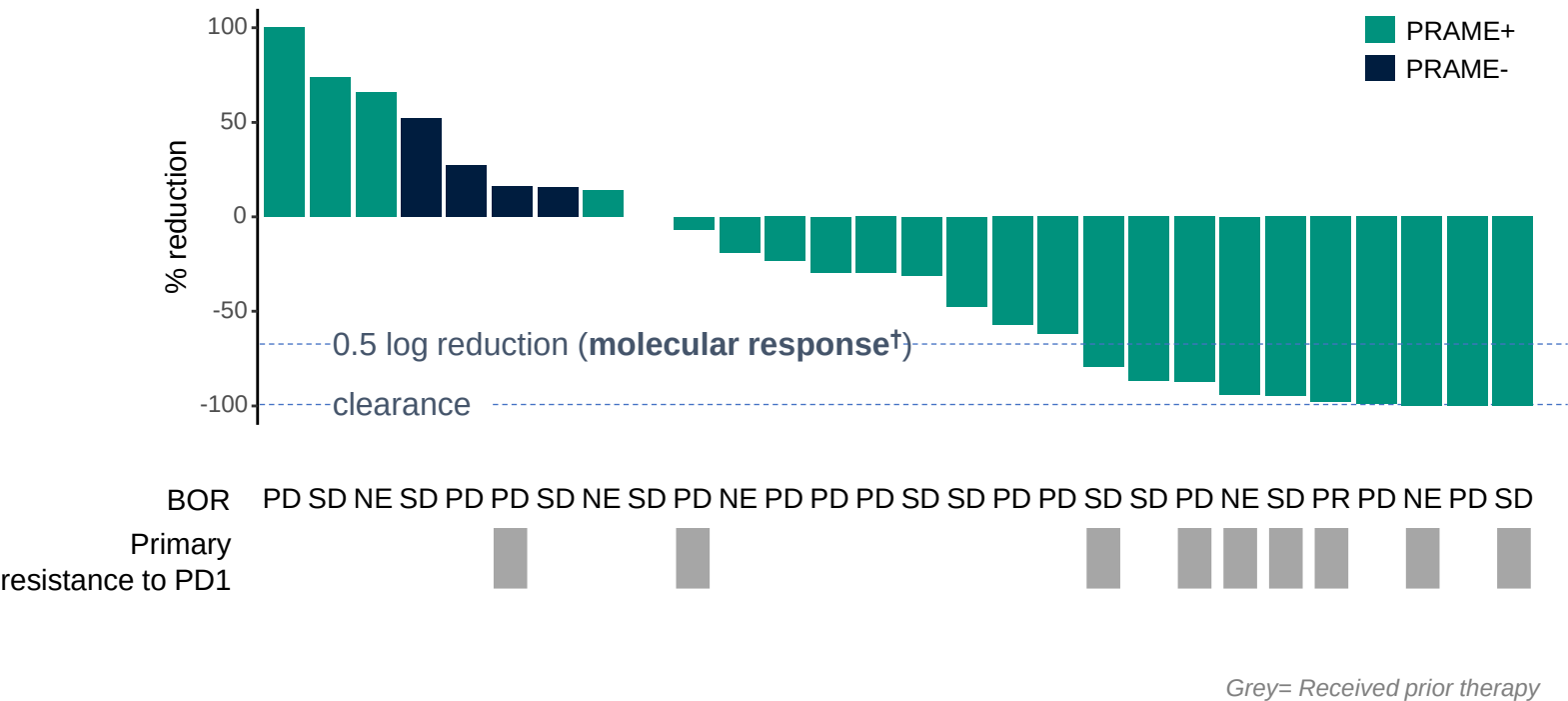
Tumor reduction observed in patients with liver and brain mets

Brenetafusp monotherapy (n= 36 evaluable)



ctDNA molecular response in 42% of PRAME+ patients

Brenetafusp monotherapy (n=28 ctDNA evaluable*)



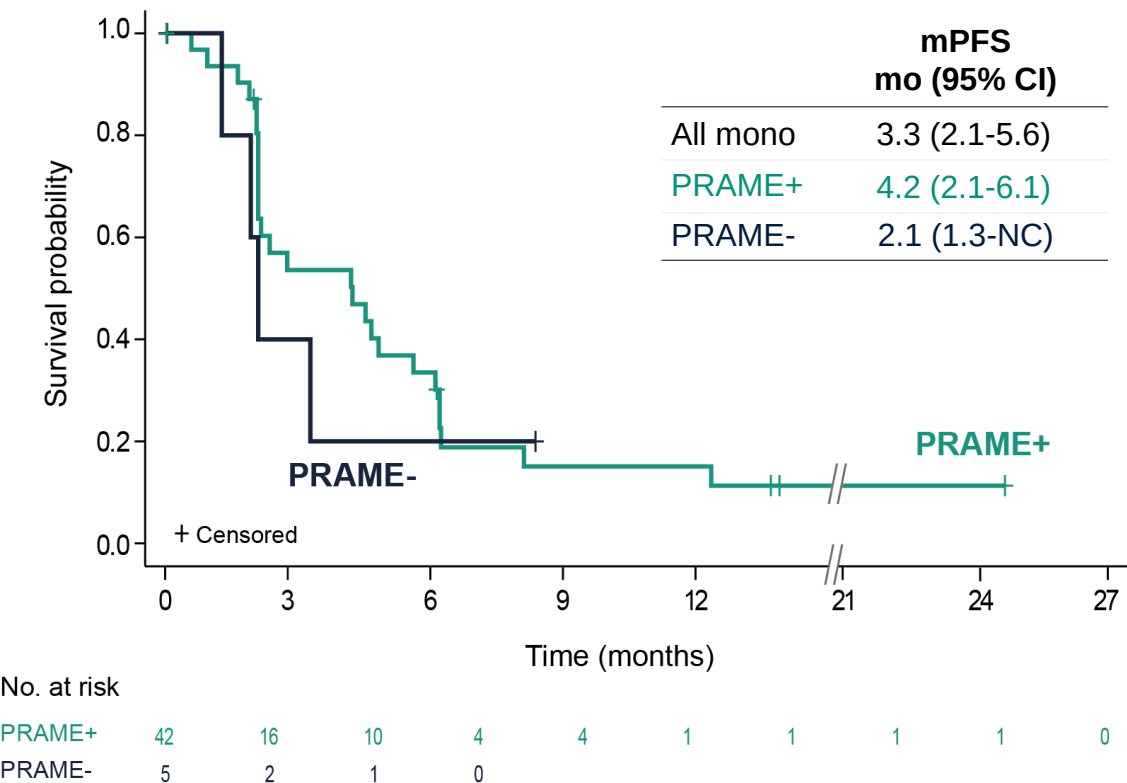
- Trend for longer PFS (HR 0.5) and OS (HR 0.3) in molecular responders
- Molecular response in patients with PR, SD and PD
- 4 pts have ≥99% ctDNA reduction

PRAME positive group includes H-score ≥1 and pts with unknown PRAME IHC results
* ctDNA evaluable defined as ≥1 mutation detected at baseline at >0.3% VAF AND data from at least one on-treatment timepoint up to week 9; n=28 ctDNA evaluable, best response by week 9
† Molecular response defined as ≥0.5log (≥68%) ctDNA reduction by week 9

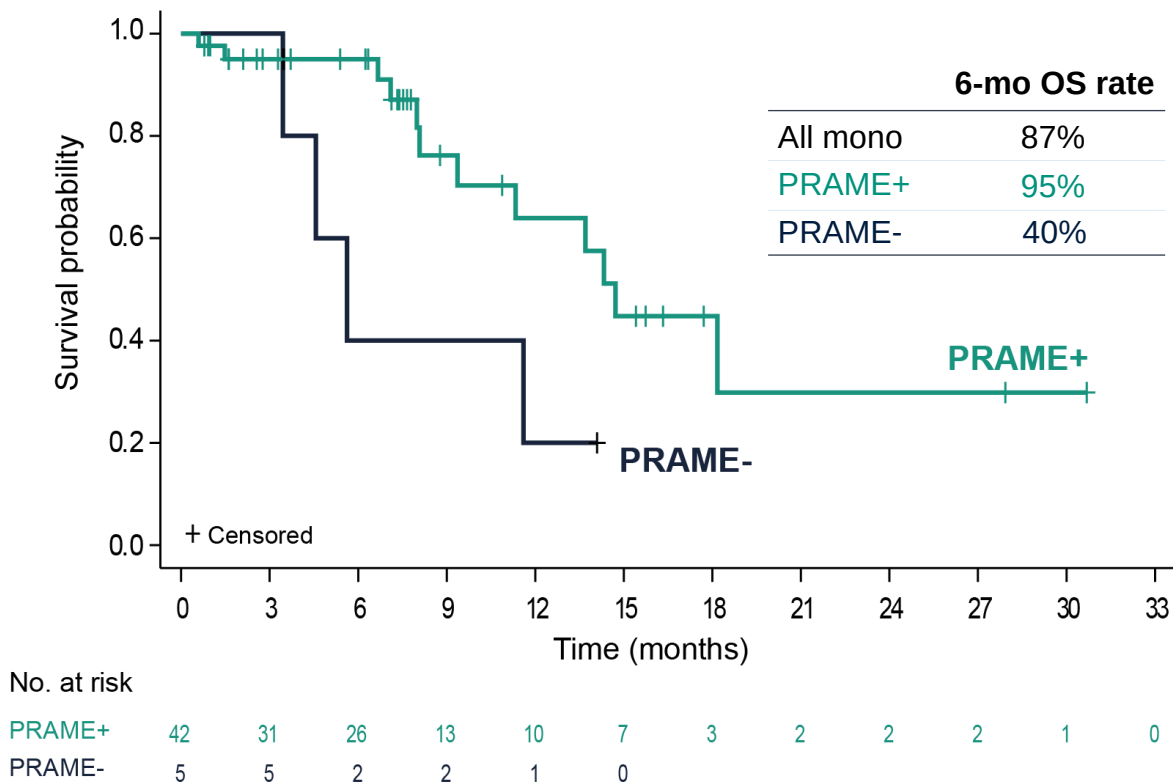
Promising initial PFS and OS, enriched in PRAME+ pts

Brenetafusp monotherapy (n= 47)

Progression free survival



Overall survival



Median follow up 7.8 mos

PRAME positive group includes H-score ≥1 and pts with unknown PRAME IHC results

Initial data for anti-PD1 combination shows well tolerated profile

Brenetafusp + pembrolizumab dose escalation safety cohort (n=9 CM patients)

Preferred Term (%)	brenetafusp + pembrolizumab	
	Any grade (N=9)	Grade 3 / 4 (N=9)
ANY	9 (100%)	3 (33%)
Cytokine release syndrome [†]	5 (56%)	-
Rash (composite) [‡]	5 (56%)	-
Nausea	3 (33%)	-
Fatigue	3 (33%)	-
Pruritus	2 (22%)	-
Headache	2 (22%)	-
Aspartate aminotransferase incr	2 (22%)	-
Vomiting	2 (22%)	-
Alanine aminotransferase incr	2 (22%)	-
Diarrhea	2 (22%)	-

[†] CRS graded per ASTCT 2019 criteria

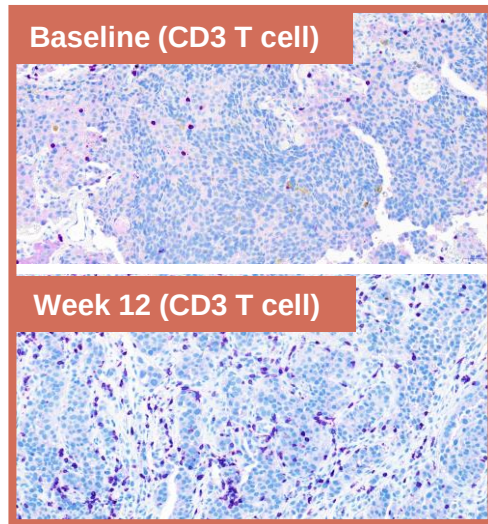
[‡] Rash is a composite term for a list of skin toxicities of any grade (Nathan *et al.* 2021)

- **Primary goal to demonstrate safety in combination**
 - Safety profile similar to each agent alone
 - 1 DLT (transaminitis) in patient with previous CPI-induced autoimmune hepatitis
- Safety profile supported by additional 12 pts dosed in combination across multiple tumors
- Secondary goal was to evaluate initial efficacy
 - 4 of 7 efficacy evaluable pts had disease control, including 1 unconfirmed PR still ongoing
 - 3 of 4 ctDNA evaluable pts had molecular response

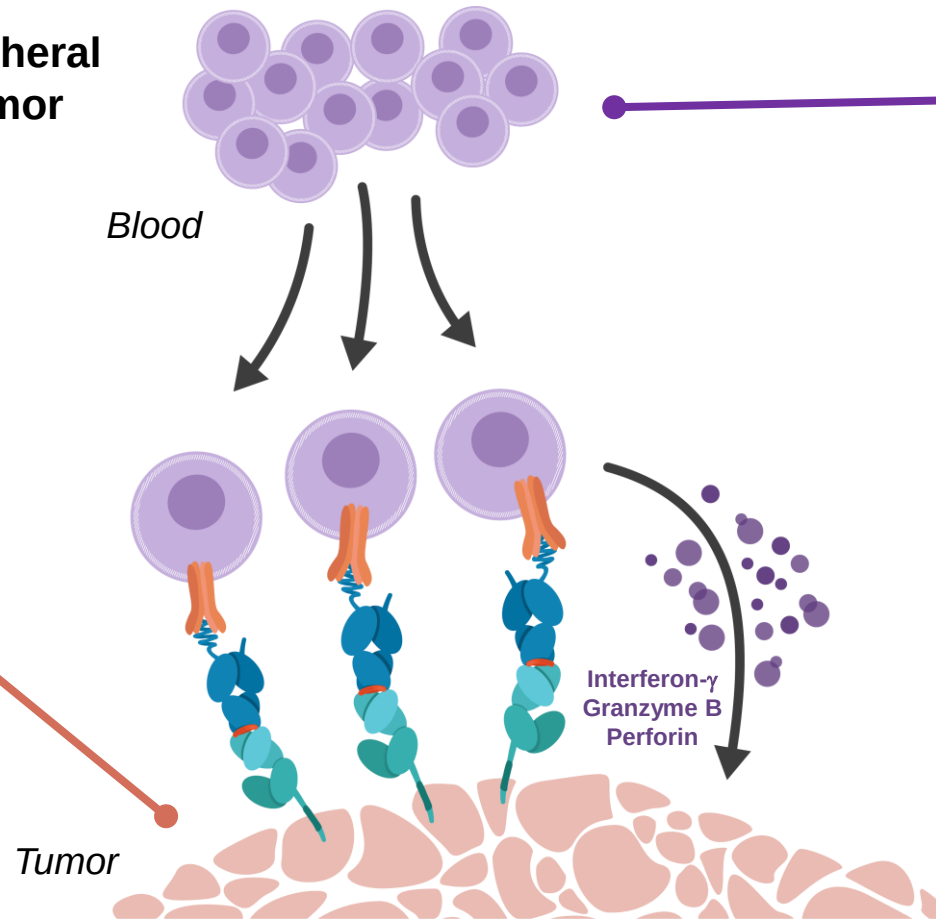
Median follow up 3.5 mos

Phenotype of peripheral blood T cells, which are recruited by brenetafusp, may be important for clinical activity

Brenetafusp recruits peripheral blood T cells into the tumor



Metastatic cutaneous melanoma



Hypothesis:

Specific T cell subsets in the blood may be associated with brenetafusp benefit

Method:

- RNAseq whole blood at baseline
- Analyzed key T cell subsets:
 - Naïve /stem cell memory T cell (T_{scm})
 - Effector
 - Exhausted
 - Regulatory

Naïve T/T_{scm} have been associated with anti-tumor activity of other T cell therapies¹.

Tscm, stem cell memory T cell

1. Gattinoni, et al. Nature Rev Cancer 2012; 12:671-684; Kishton, et al. Curr Opin Imm 2022; 74:39-45; Mehta, et al. Front Immunol 2021; 12:780442; Arcangeli, et al. J Clin Invest 2022; 123:e150807; Rosenberg, et al. Clin Cancer Res 2011; 17:4550-4557

Novel T cell fitness (TCF) signature associated with brenetafusp benefit

TCF higher in earlier lines of therapy and highly correlated with naïve/T_{scm} cells

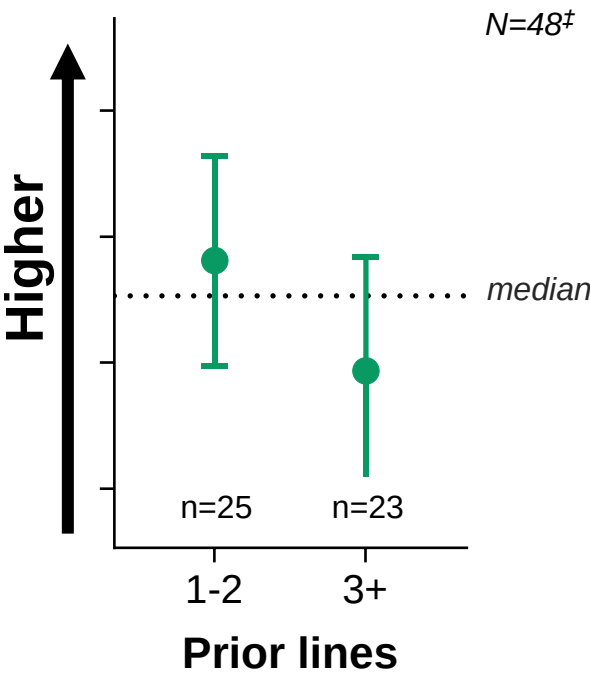
Monotherapy benefit by TCF signature

	High*	Low
N=41 [†]	n=21	n=20
mPFS	6 mo	2 mo
ORR	19%	0%
DCR	69%	42%

* For exploratory analysis, 'high' defined as ≥ median gene expression signature level

Other gene signatures, including T effector and exhausted T cell phenotype, not associated with clinical benefit (data not shown)

TCF signature, by line of therapy



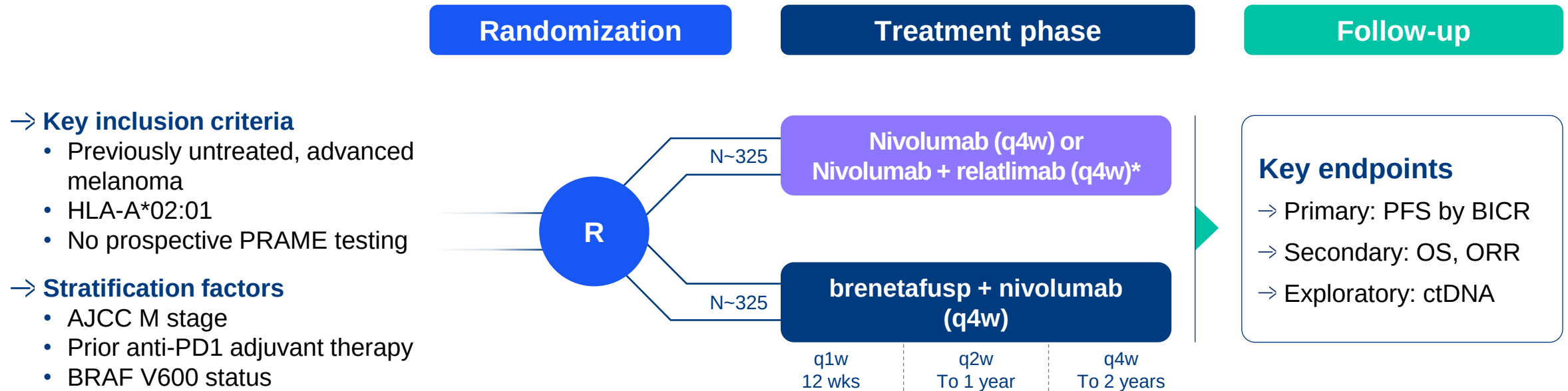
[†] 41 monotherapy CM patients had baseline TCF and were evaluable for tumor assessment on therapy;
[‡] 42 monotherapy CM and 6 pembrolizumab combination patients had baseline T cell fitness evaluated

Conclusions

- Brenetafusp is well tolerated
 - Most frequent TRAE is reversible and manageable CRS (Grade 1-2)
 - Brenetafusp can be safely combined with anti-PD1
- Promising monotherapy activity in heavily pretreated CM supports a PFS endpoint
 - Enriched in PRAME+: DCR (58%), confirmed tumor reduction (32%), molecular response (42%) and mPFS (4.2mo)
 - These endpoints best capture brenetafusp benefit and are consistent across ImmTAC platform¹⁻³ (2024 ASCO poster #9529)
- T cell fitness signature associated with brenetafusp benefit and higher in earlier lines of therapy
 - This association emerging across ImmTAC platform and reported for other T cell therapies⁴
- Data support Ph3 brenetafusp + nivolumab in 1st line mCM (PRISM-MEL301; NCT06112314)

1. Nathan P, *et al.* N Engl J Med 2021;385:1196-206; 2. Hassel JC & Piperno-Neumann S, *et al.* N Engl J Med 2023; 389:2256-2266; 3. Carvajal RD, *et al.* Nat Med 2022; 28:2364-2373 4. Gattinoni, *et al.* Nature Rev Cancer 2012; 12:671-684; Kishton, *et al.* Curr Opin Imm 2022; 74:39-45; Mehta, *et al.* Front Immunol 2021; 12:780442; Arcangeli, *et al.* J Clin Invest 2022; 123:e150807; Rosenberg, *et al.* Clin Cancer Res 2011; 17:4550-4557

PRISM-MEL301: First-line advanced CM Phase 3



Initial randomization includes comparison of two brenetafusp regimens (~90 patients or 30/arm)

(PRISM-MEL301; NCT06112314); see ASCO 2024 TiP poster #TPS9602

* Use of nivolumab or nivolumab + relatlimab as control will be country specific

Thank you to all patients, their families and their caregivers who were involved in this global clinical trial & all investigators and their teams



Omid Hamid

Takami Sato
Diwakar Davar
Benjamin Izar
Daniel Olson

Claire Friedman
Vincent Ma

The Angeles Clinic and Research Institute, A
Cedars-Sinai Affiliate
Thomas Jefferson University Hospitals
University of Pittsburgh Medical Center
Columbia University Medical Center
University of Chicago, Comprehensive Cancer
Center
Memorial Sloan Kettering Cancer Center
University of Wisconsin Carbone Cancer Center



Juanita Lopez

Anja Williams
Fiona Thistlethwaite

Heather Shaw
Mark Middleton

Royal Marsden NHS Foundation Trust and Institute
of Cancer Research
Sarah Cannon Research Institute, London
The Christie NHS Foundation and University of
Manchester
University College London
University of Oxford



Celeste Lebbe

Université Paris Cité, Hôpital Saint-Louis, INSERM



Peter Lau
Georgina Long

Linear Clinical Research, Harry Perkins Institute for
Medical Research, Nedlands, WA, Australia



Oliver Bechter
Bart Neyns

UZ Gasthuisberg - Katholieke University Leuven
Universitair Ziekenhuis



Gennaro Daniele

Fondazione Policlinico Universitario Agostino Gemelli
IRCCS



Catherine Han

New Zealand Clinical Research – Auckland



Piotr Tomczak

Centrum Medyczne Pratia Poznan

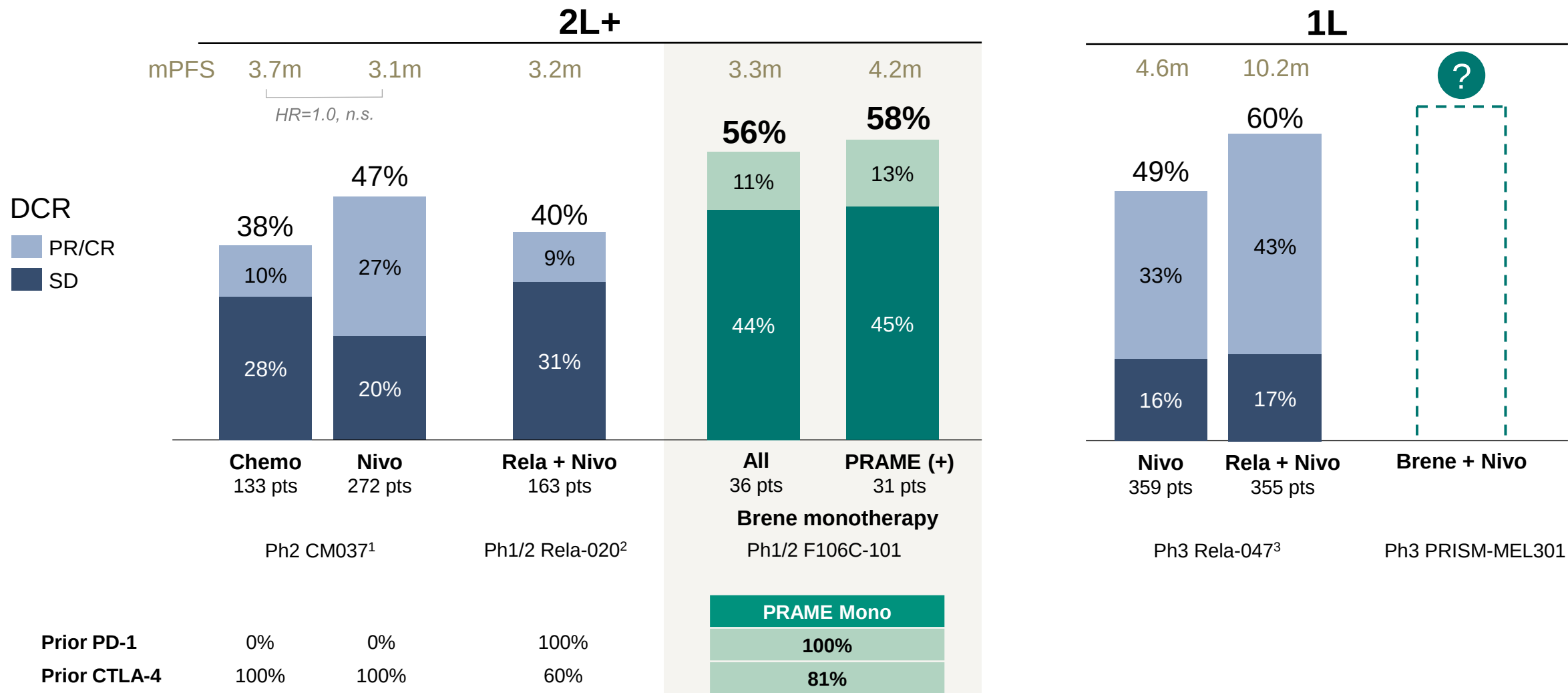


Dong-Wan Kim
Dae Ho Lee

Seoul National University Hospital
Asan Medical Center

Multiple lines of evidence supports 1L Ph3 combo (nivo + brene)

High monotherapy DCR in 2L+ | ImmTAC activity higher in 1L | Combination with nivolumab in 1L



Note: data for informational purposes, no comparative claims are implied or intended. Nivo: nivolumab; Rela: relatlimab; 1. CM037: [NCT01721746](#), Larkin J, et al. J Clin Onc 2018; 2. RELA020, [NCT01968109](#): D2 Cohort (≥1 anti-PD-(L)1 containing regimen), Ascierto PA, et al. J Clin Onc 2023. 3. RELA047: [NCT03470922](#), Long GV, et al. NEJM 2023

Melanoma franchise

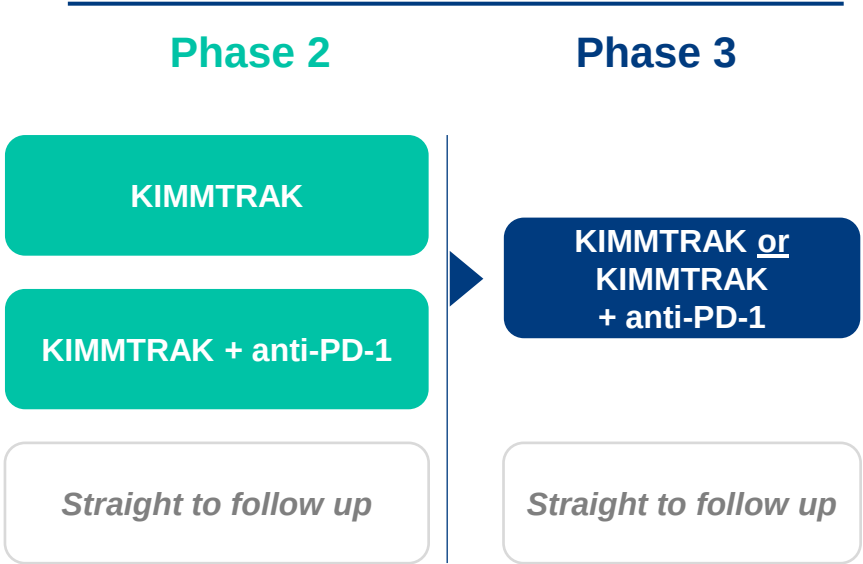


IMMUNOCORE

TEBE-AM trial now conducted as a Ph3

All patients randomized to date included in ITT following FDA consultation

Original Design (Ph2/3)



Phase 3 endpoint

OS

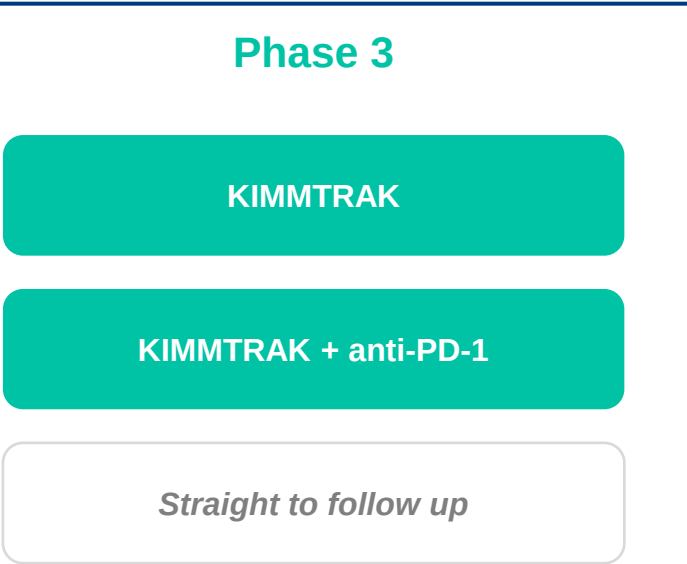
Eligibility

Prior anti-PD1, ipilimumab, BRAF (if mutation positive)

Experimental arms

KIMMTRAK or
KIMMTRAK + anti-PD1

Updated Design (Ph3)



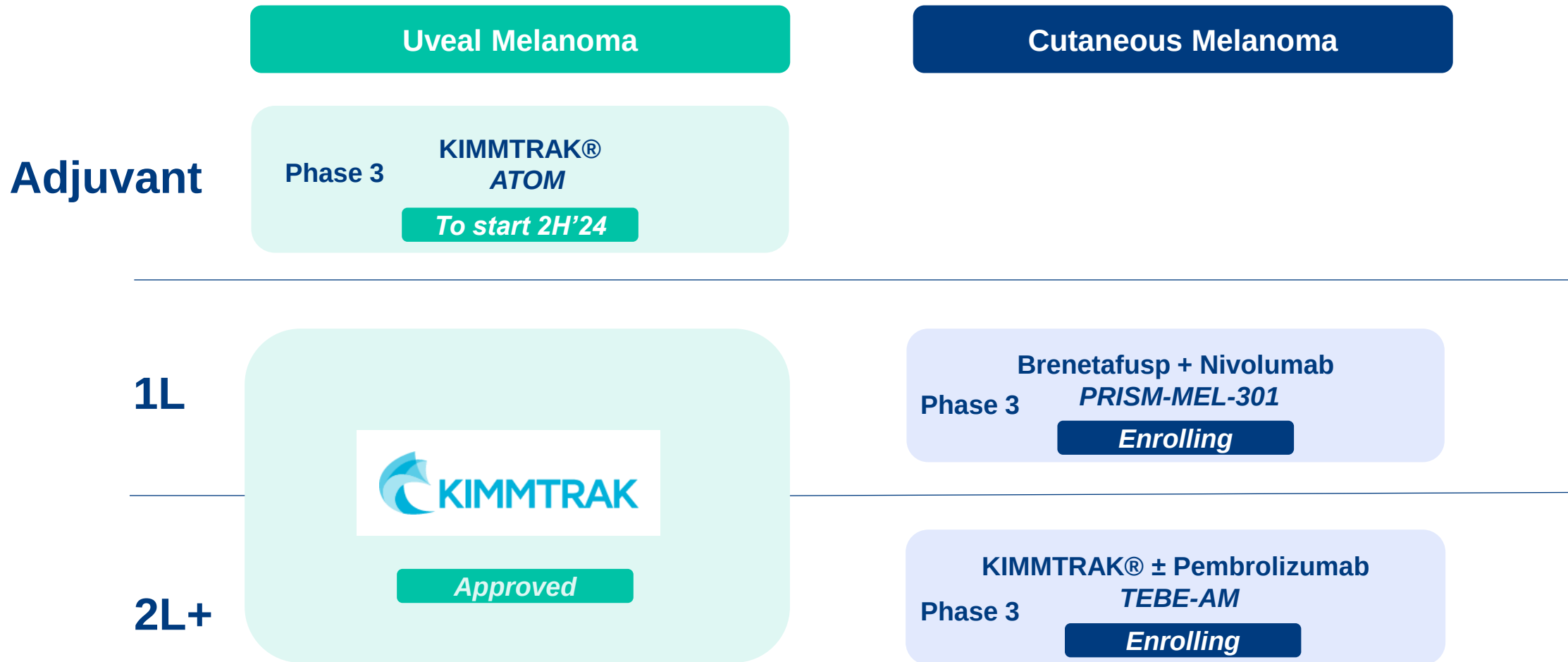
OS

Unchanged from original design

KIMMTRAK and
KIMMTRAK + anti-PD1

- Leverages recent rapid accrual
- More robust evaluation of two KIMMTRAK regimens: As monotherapy and as anti-PD1 combination
- Faster time to final OS analysis since all patients randomized to date to be included

Building ImmTAC melanoma franchise with three Phase 3 trials



Q&A Session



Bahija Jallal
PhD

Chief Executive Officer



Brian Di Donato

Chief Financial Officer
and Head of Strategy



David Berman
MD, PhD

EVP, Research and
Development



Ralph Torbay

Head of
Commercial



Mohammed Dar
MD

SVP, Clinical Development
and Chief Medical Officer



Koustubh Ranade
PhD

SVP, Translational Medicine