Society for Immunotherapy of Cancer

40TH ANNIVERSARY SITC 2025

Nov. 5–9 | National Harbor, MD

40th Anniversary Annual Meeting & Pre-Conference Programs

40 Years of Driving Breakthroughs in Cancer Immunotherapy.

#SITC25

SCOPE, a phase 2 trial with DNA plasmid immunotherapy in advanced melanoma combined with check point blockade

An interim read-out of SCOPE, an open label parallel multi cohort translational study evaluating an off-the-shelf DNA plasmid vaccine in first line advanced melanoma combined with check point blockade.

Abstract Number: 1325

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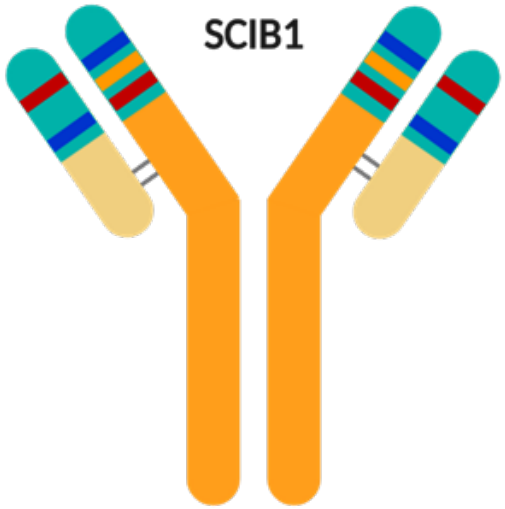
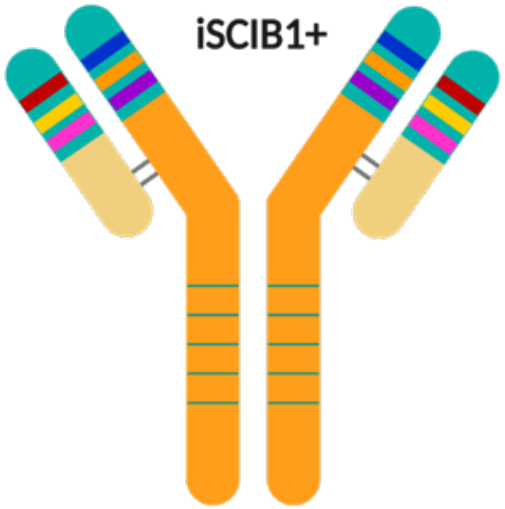
Disclosures

- Serve as full time Chief Medical Officer at Scancell Ltd, UK – study sponsor

SCIB1 & iSCIB1+ are off-the-shelf DNA plasmid vaccines with CD8 & CD4 epitopes from TRP-2 and gp100.





SCIB1	Amino acids
✓	H1: gp100 173-190
✓	H2: TRP2 180-188
	H3: gp100 471-492
✓	L1: gp100 44-59
	L2: TRP2 177-205
	L3: TRP2 60-91

Amino acids	iSCIB1+
A2/DR7/DR53/DQ6	✓
A2	✓
DP4/A1/B35	✓
DR4	✓
A2/DP4/A31/A33/A3	✓
DR3/B35/B44	✓

- SCIB1 and iSCIB1 + incorporate CD8 and CD4 epitopes from TRP-2 and gp100 into an antibody framework to allow direct and Fc targeting of activated dendritic cells
- TRP-2 and gp 100 epitopes that have a key role in melanin production were isolated from T-cells of patients with spontaneous recovery from melanoma
- Next generation iSCIB1 + has additional epitopes applicable to more HLA MHC – class 1 haplotypes, **A2, A3, A31, Bw4, B35 & B44** that represent 80% of the population
- iSCIB1+ is modified for additional avidity with long Intellectual Property protection

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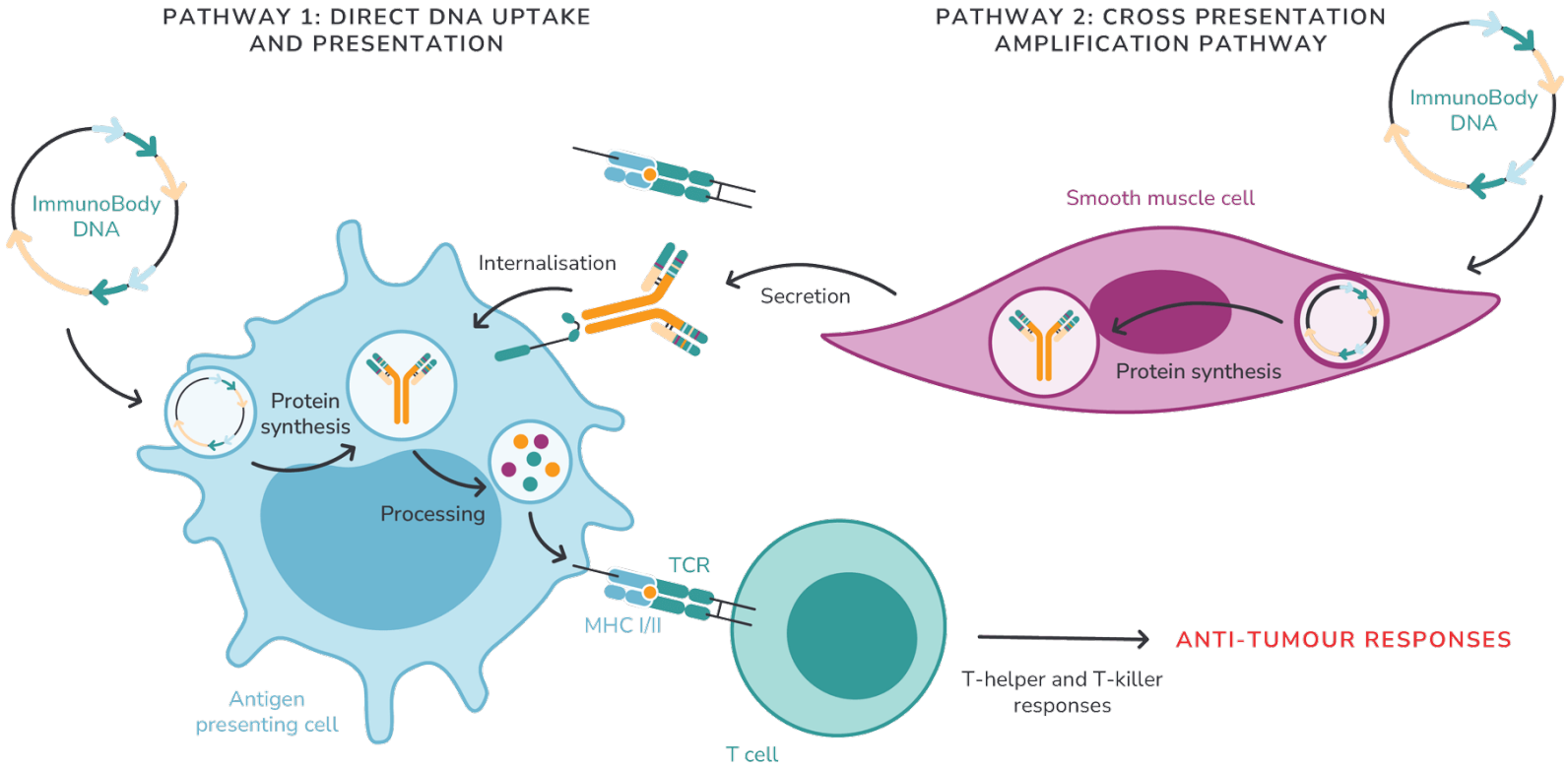
Dual mode of action to maximise anti-tumour immune response following needle free injection



- By **Direct Presentation** ImmunoBody targets antigen presenting cells (APCs) via CD64 causing expression of engineered antibodies
- By **Cross Presentation** secretion of the engineered antibody targeted to CD64 FcγR present on APCs via its Fc domain.
- On binding with specific T-Cell Receptors mediated by MHC class1, CD-8 killer and CD-4 memory / helper anti-tumour response occurs

SCOPE Program - advanced melanoma with checkpoint inhibitors

Phase 2 open label multi cohort translational study enrolling over 140 patients with start in 2022.
Objective: select product, target population, dosing schedule and endpoints for follow-on phase 3 trial

STUDY POPULATION

Advanced melanoma in combination with standard of care Check Point Blockade

Inclusion Criteria (Summary)

- Histologically confirmed, unresectable Stage III or Stage IV Melanoma
- Not received prior systemic treatment for advanced disease.
- ECOG Performance Status 0 or 1.
- At least one measurable RECIST 1.1 lesion
- HLA status known

Exclusion Criteria (Summary)

- Acral, Ocular & Mucosal Melanoma
- CNS Metastases
- Exposure to CPI as adjuvant treatment in previous 6 months

Cohort 1 (n=43)

SCIB1 and SoC nivolumab & ipilimumab
Target HLA (A2 haplotype only)

Cohort 2 (n=10) stopped due to change in SOC

SCIB1 and SoC pembrolizumab
Target HLA (A2 haplotype only)

Cohort 3 (n=50, 39 Matched HLA, 11 Non-matched)

iSCIB1+ and SoC nivolumab & ipilimumab

Cohort 4 (n=31, 24 Matched HLA, 7 Non-Matched)

iSCIB1+ with accelerated priming and SoC nivolumab & ipilimumab

Seek to improve reported outcomes with SOC CPI

(Efficacy, Durability, Safety)

Nivolumab & ipilimumab:

- PFS: 46% at 12 mths
- ORR: 50% (checkmate 067) and 48% (RWE)
- Grade 3 Adverse Events in 53% of patients

Pembrolizumab:

- ORR: 41% (Keynote-001)
- PFS: 35% at 12 months
- Grade 3 Adverse Events in 14% of patients

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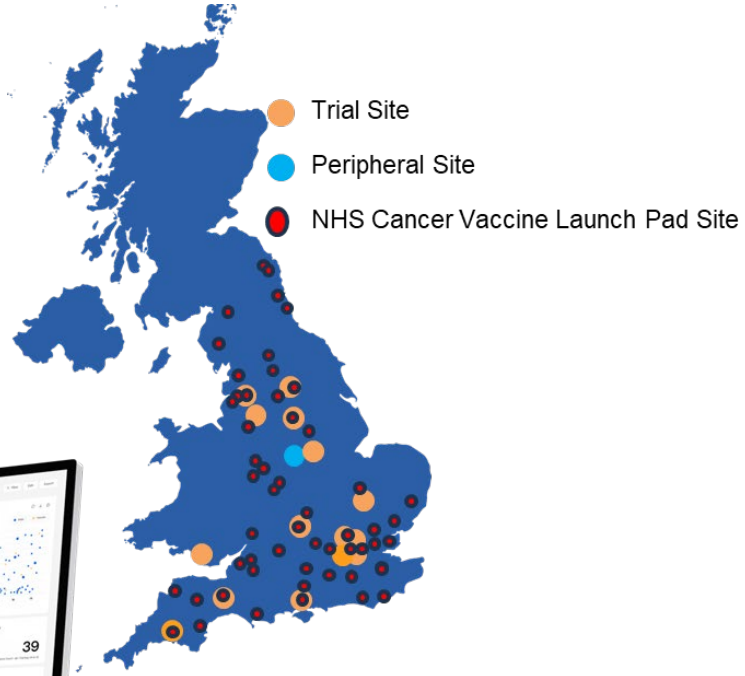
ORR = overall response rate, SoC = Standard of Care

SCOPE: Study Partners and Schema

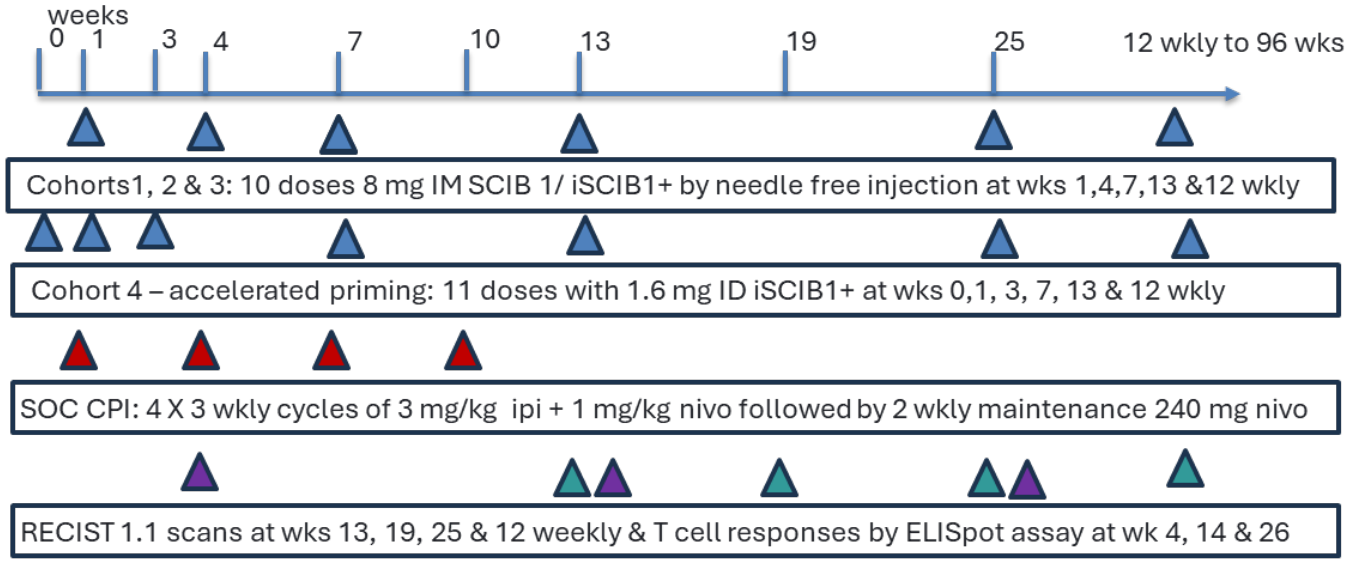
Conducted at 16 UK Clinical Trial Sites

Partnership with NHS Cancer Vaccine Launch Pad to enable NHS patient enrolment across England and Wales



Adoption of Rivia, a unified data and analytics platform to integrate fragmented trial data in real time allowing for actionable insights.

Study Schema & Dosing Schedule



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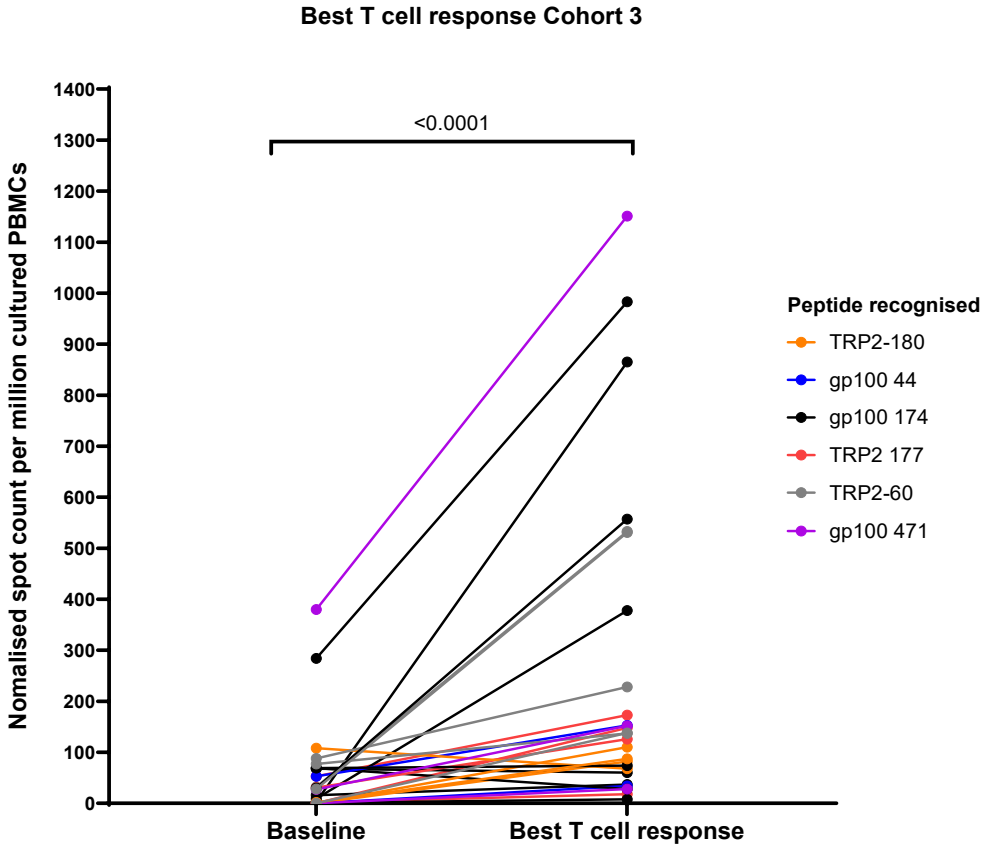
Across cohorts in HLA matched patients there were strong T cell responses correlated with clinical response.

T-cell Responses - ELISpot Assays (n=33)

CLINICAL RESPONSE	NUMBER OF PATIENTS	POSITIVE T CELL RESPONSE	% POSITIVE
CR/PR	19	15	79%
SD	7	5	71%
PD	7	4	57%

- 19/31 (61%) HLA matched patients made a T-cell response
- 15/19 (79%) amongst clinical responders
- 10/12 (83%) with a CD8 response were clinical responders



- All six iSCIB1+ epitopes generated CD8 T cell responses
- 72% of patients responded to both TRP-2 & gp100 reducing risk of immune escape

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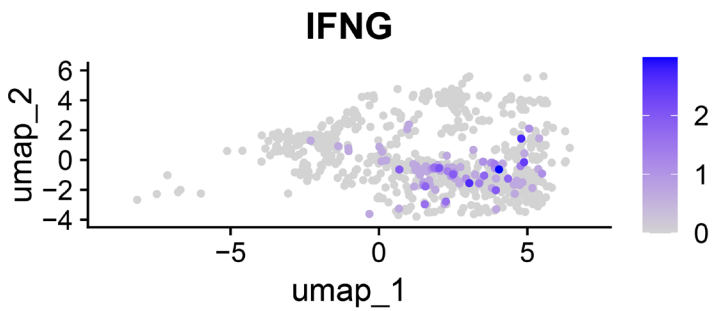
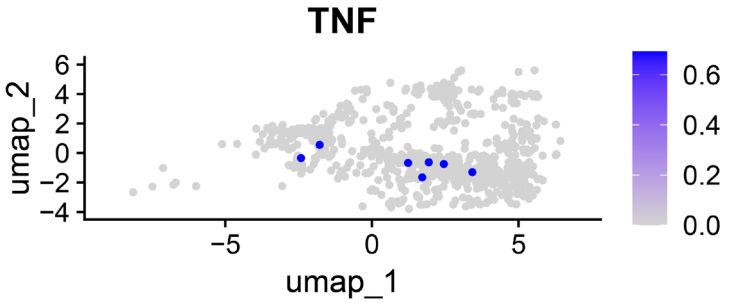
Cells with iSCIB1+ reactive TCRs show strong cytotoxic signature

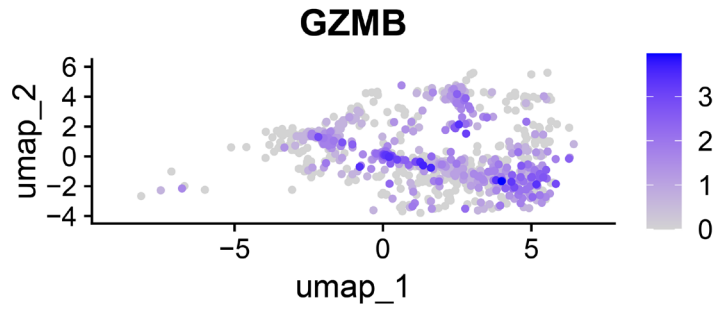
888 IFNγ+ CD8 T cells from 5 patients

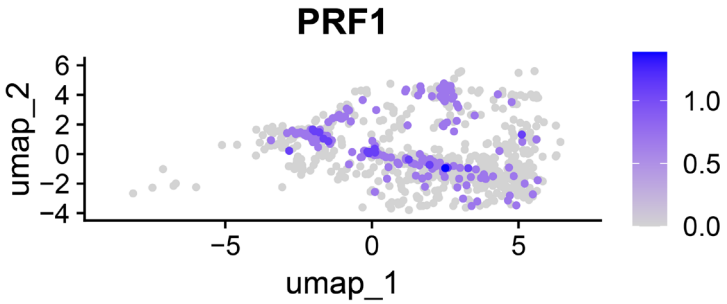
Functionality

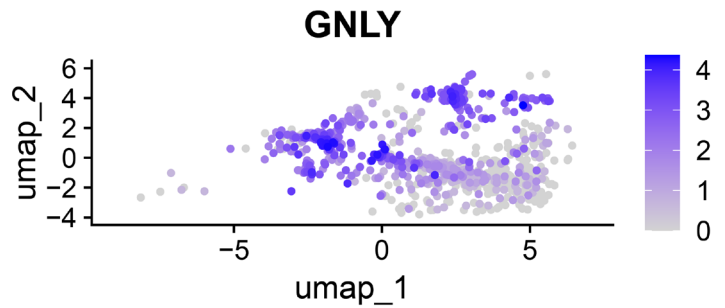




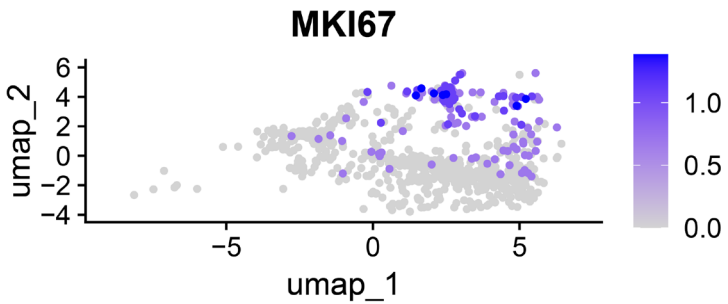
Killing







Proliferation

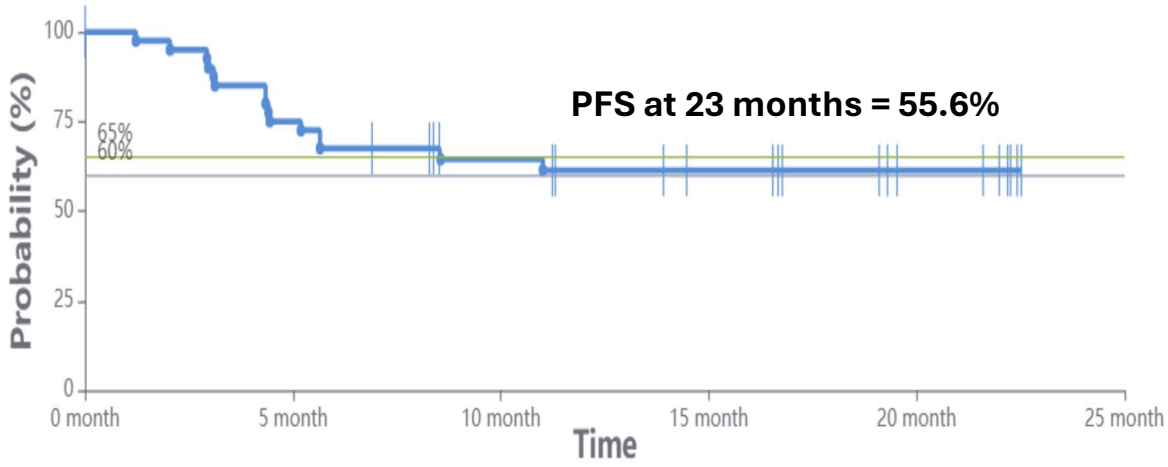


One dot per cell
Grey = no expression

Strong expression of granzyme B, perforin confirms CD8 activation.

Clinical Response with SCIB1 in cohort 1: Interim Read-Out

Progression Free Survival (n=41)

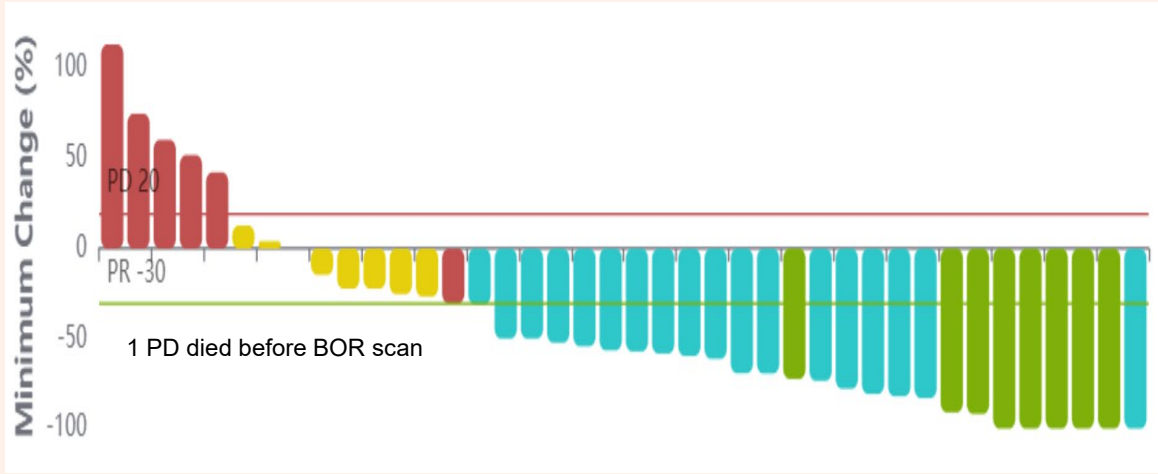


Median PFS for checkmate 067 = 11.5 mths, not reached here

PFS at 12 mths: 46% for nivolumab & ipilimumab vs 60% on addition of SCIB1

RECIST 1.1 Best Overall Response: Waterfall Plot

PD	SD	PR	CR	RESPONSES
7	8	18	8	ORR: 63.4% (26/41) DCR: 82.9% (34/41)



Average Change (%)

Interim Data Read-Out 22nd July 2025

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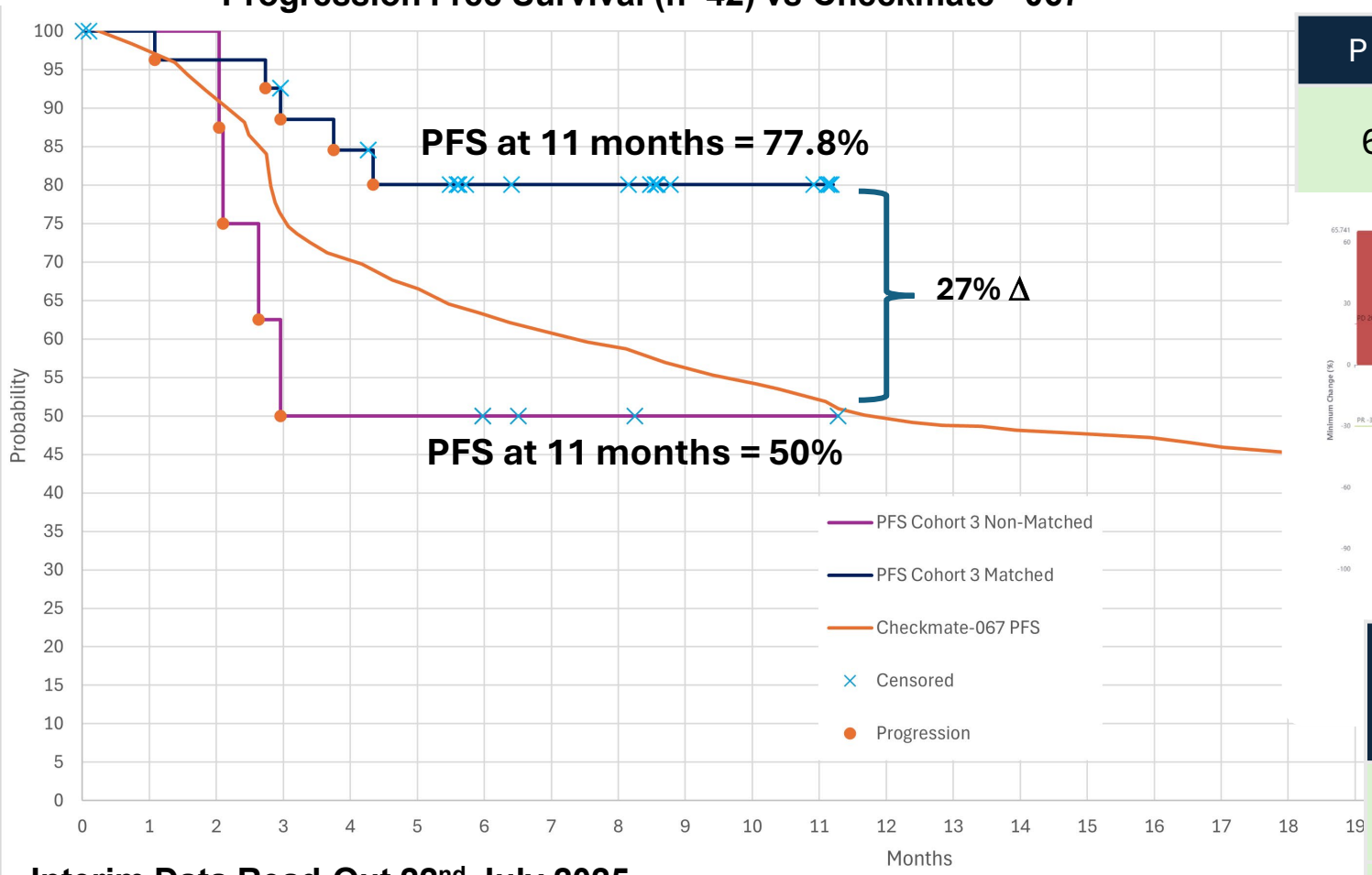
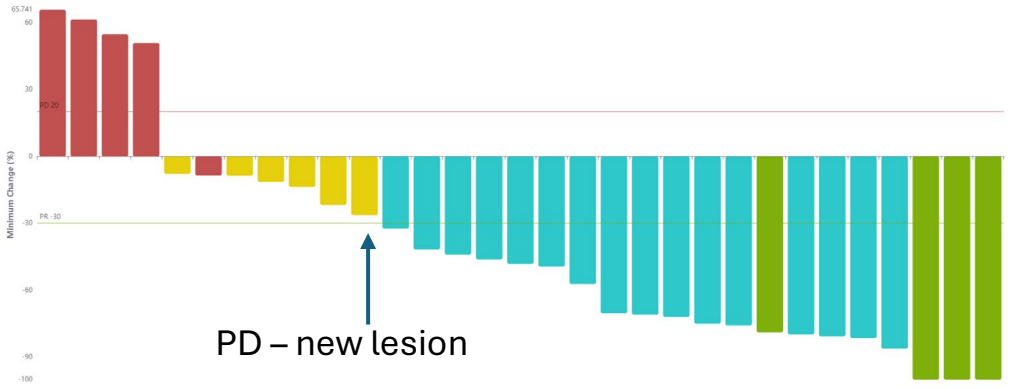
Clinical Response with iSCIB1+ in cohort 3: Interim Read-Out

Progression Free Survival (n=42) vs Checkmate - 067



RECIST 1.1 Best Overall Response: Waterfall Plot

PD	SD	PR	CR	RESPONSES
6	5	16	4	ORR: 64.5% (20/31) DCR: 80.6% (25/31)



HLA	Patients Immunised	Patients Awaiting 1st Scan	RESPONSES
Matched	38	7	ORR: 64.5% (20/31) DCR: 80.6% (25/31)
Non-matched	11	0	ORR: 27% (3/11) DCR: 54.5% (6/11)

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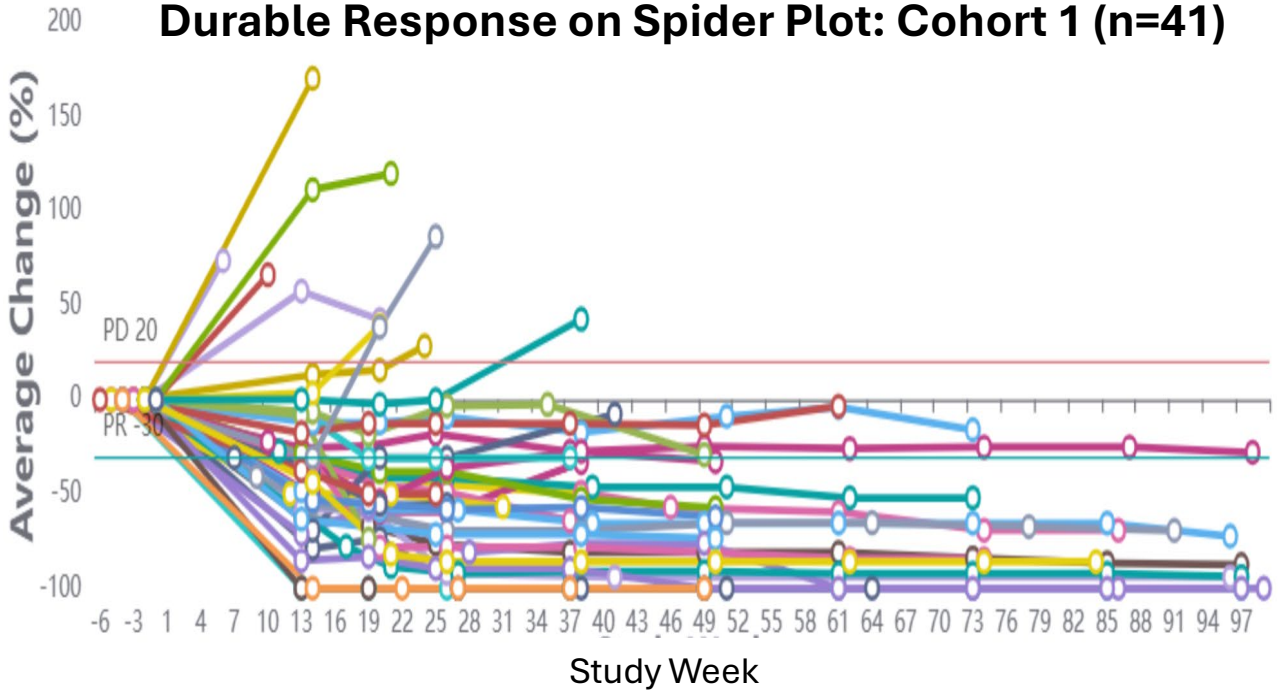
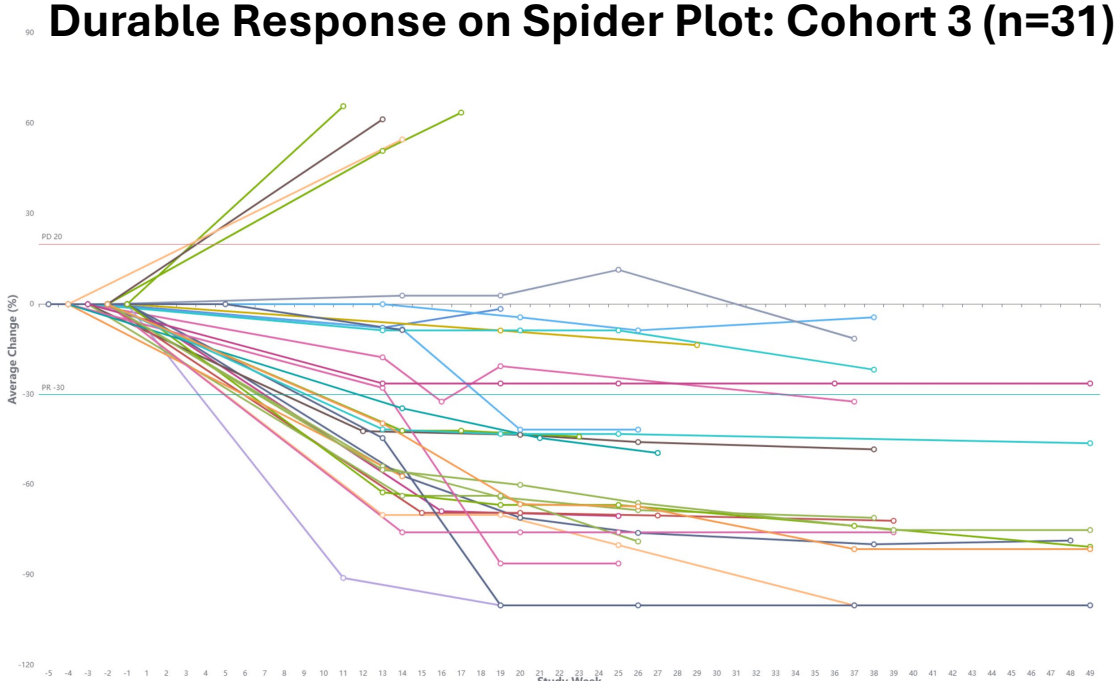
Durable Response with SCIB & iSCIB1+ amongst matched HLA patients in Cohorts 1&3.

Durable Response on Spider Plot: Cohort 1 (n=41)

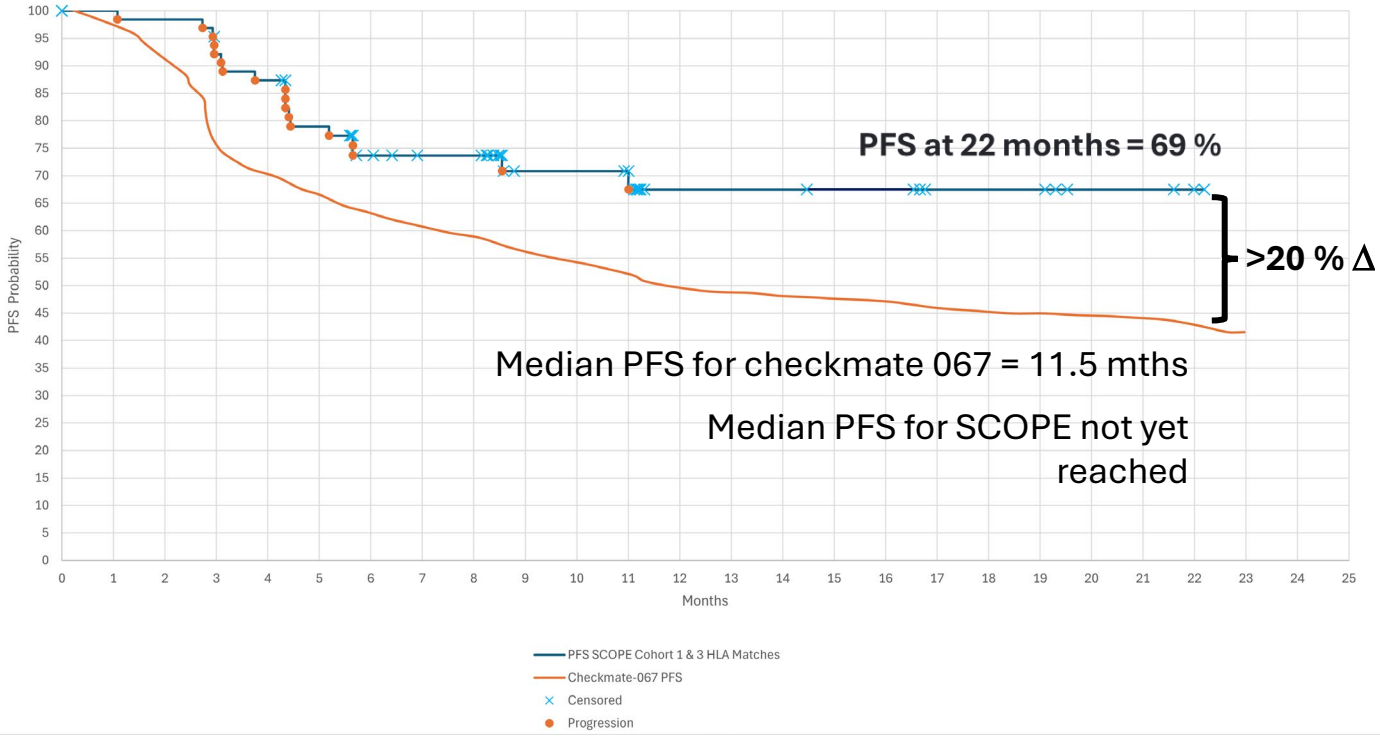


Durable Response on Spider Plot: Cohort 3 (n=31)

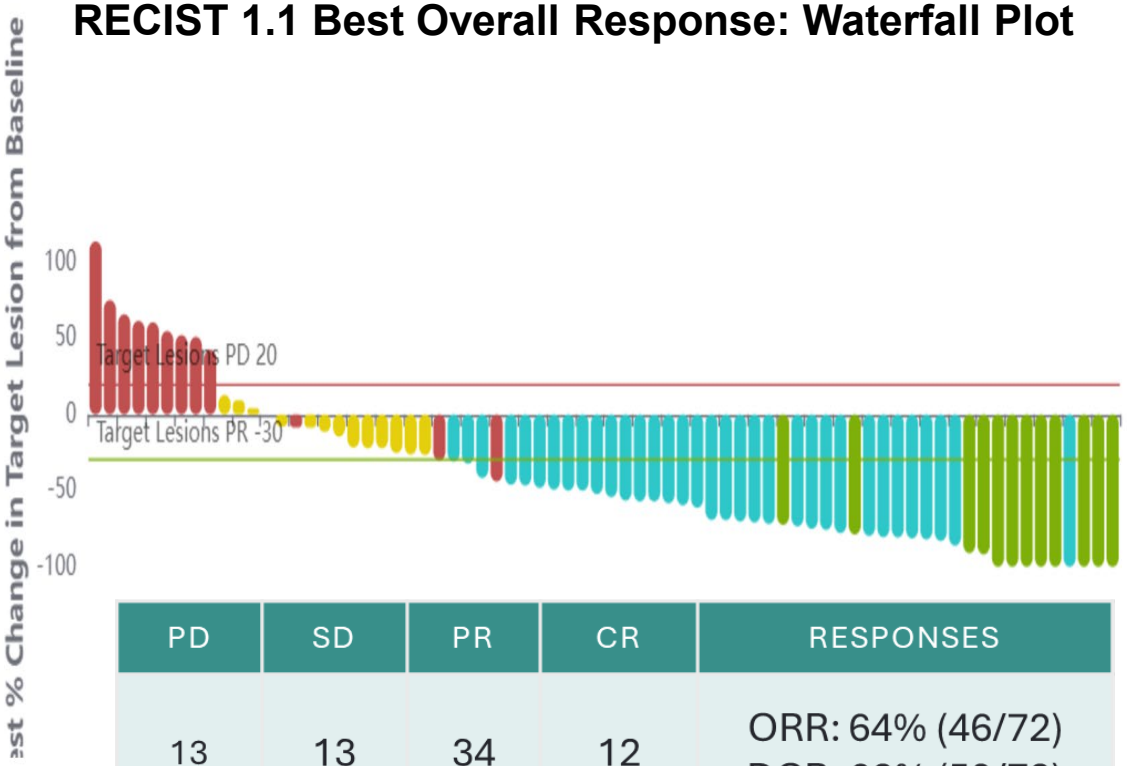


Clinical Response in HLA matched patients with SCIB1 / iSCIB1+ in cohorts 1 & 3: Interim Read-Out

Progression Free Survival (n=72) vs Checkmate – 067



RECIST 1.1 Best Overall Response: Waterfall Plot



PD	SD	PR	CR	RESPONSES
13	13	34	12	ORR: 64% (46/72) DCR: 82% (59/72)

Interim Data Read-Out 22nd July 2025

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Interim Safety Summary – SCIB1 and iSCIB1+ (n = 133)

The safety profile of SCIB1 / iSCIB1+ is benign with no potentiation of the toxicities of the checkpoint inhibitors.

	Related to SCIB1 or iSCIB1+	Related to checkpoint inhibitors
TEAE	292 in 75 (56%) patients Majority comprised of elevated ALT/AST, injection site bruising, gastrointestinal & skin disorders	867 in 116 (87%) patients Majority comprised of elevated ALT/AST, gastrointestinal and skin disorders
TEAE ≥ G3	31 in 18 (13%) patients SCIB1 = 14 & iSCIB1+ = 17	121 in 68 (51%) patients
SAEs	11 in 10 (7%) patients All SUSARs are dually related to CPI therapy; No SUSARs are reported as only related to SCIB1 or iSCIB1+.	94 in 58 (43%) patients

Conclusions and Next Steps

- Efficacy benefit, Durability & Tolerability of iSCIB1+ confirmed with Progression Free Survival improvement set to be a critical end point
- HLA matched population with either MHC – class 1 A2, A3, A31, Bw4, B44, B35 comprising 80% of the patient population identified
- Stable off-the-shelf product delivered IM by needle free injection with an accelerated priming dosing schedule
- Await further data with its maturity + Follow-on phase 3 registration RCT planned along with evaluation in the neoadjuvant setting
- Potential to re-define treatment paradigm for malignant melanoma

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Acknowledgements and Appreciation

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