



DEVELOPING ANTIBODIES AND VACCINES FOR CANCER

Advancing Cancer Immunotherapy

Business Update and Results for Year Ending 30th April 2024

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24 September 2024

LSE: SCLP.L

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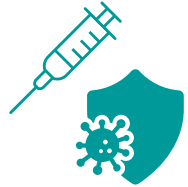
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- ▶ **Positive efficacy signals from lead cancer vaccines with near-term clinical milestones**
 - ▶ SCIB1 with doublet CPI for unresectable melanoma exceeds 70% expectation with reported results in 13 patients
 - ▶ SCOPE study recruitment at 36 for SCIB1 and 27 for iSCIB1+
 - ▶ Modi-1 safe as a monotherapy with 60% patients showing stable disease & now in RCC cohort with doublet CPI therapy
 - ▶ SCIB1 data expected Q4 2024 and iSCIB1+ and Modi-1 data expected H1 2025



- ▶ **Well prepared and well positioned for the next stages for development**
 - ▶ 2025 is a pivotal time to demonstrate a new clinical benchmark with SCIB1/iSCIB1+ for advanced melanoma
 - ▶ Global medical oncologists have reviewed and strengthened Scancell's plan for a Phase 2/3 registration study
 - ▶ Prepared for next steps of development with strategic partnership with PharmaJet secured & GMP batch progressing
 - ▶ Enhanced organisational capabilities with recruitments for business development, manufacturing, CFO and CMO



- ▶ **Cash runway through to Q3 2025, with upside opportunities, beyond value creating milestones**
 - ▶ Upside opportunities with exclusive antibody evaluation from major international biotech & SC129 on track with Genmab
 - ▶ Financing late 2023 raised gross proceeds of £11.9 million with participation from existing & new life science investors
 - ▶ Convertible Loan Notes maturity dates extended post-period by two years with positive cash impact

Pipeline: Multiple Value Drivers with Therapeutic Potential

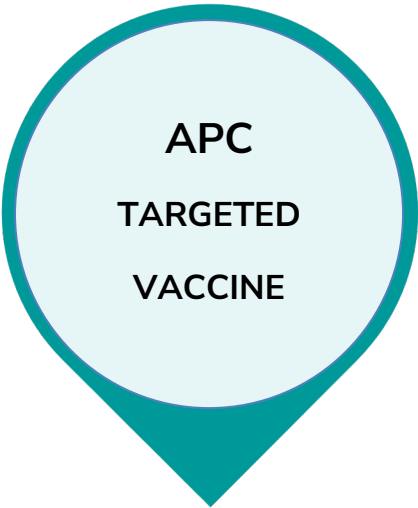


Near-term focus on Scope & ModiFY study

		Indication	Preclinical	Phase 1	Phase 2	Phase 3	Clinical Data
VACCINES	SCIB1 / iSCIB1+ (SCOPE Study)	Unresectable Melanoma					Q4 2024/ H1 2025
	Modi-1 (ModiFY Study)	Renal cell carcinoma, Head & Neck, Ovarian, TNBC					H1 2025
	iSCIB2	Multiple solid tumours					
	Modi-2	Multiple solid tumours					
ANTIBODIES	SC129	Pancreatic, GI Cancers					Out licensed to Genmab
	SC134	Small Cell Lung Cancer					
	Glymabs®	Multiple Tumours					Exclusive evaluation with Major Biotech
	AvidiMab®	Any mAB target					

Immunobody® DNA Vaccine Platform

Unlocking potential for non-personalised cancer vaccines



**APC
TARGETED
VACCINE**

Targets antigen presenting cells in vivo to give potent T cell responses, attacking cancer on multiple fronts



OFF THE SHELF

Robust GMP manufacturing process, stable shelf life and faster route to treatment allowing pricing flexibility. Five-year stability



**NEEDLE
FREE**

Delivers a spring-powered injection in 0.1 seconds by means of a narrow stream of fluid that penetrates the skin with a precise dose and depth



LOW TOXICITY

Favourable safety profile when administered as a monotherapy and in combination with checkpoint inhibitors



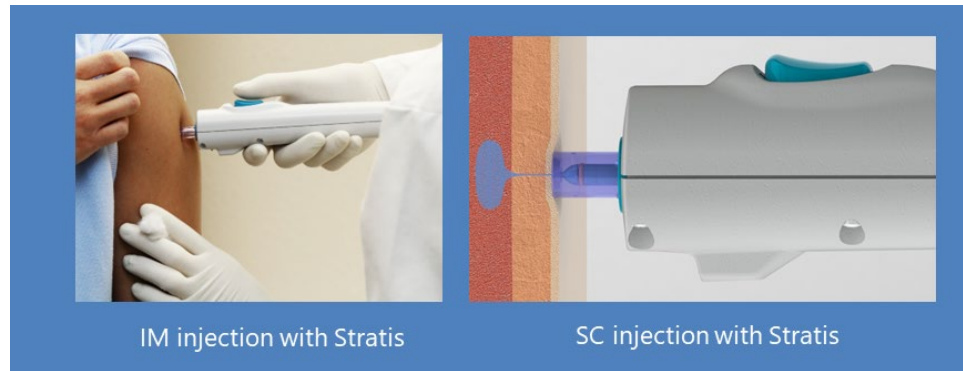
CUSTOMISABLE

DNA targets can be adapted to target other cancers. Groundbreaking science leads to validated preclinical results and rapid entry into the clinic

PharmaJet

Stratis[®] Intramuscular Needle-free delivery System for development of SCIB1/iSCIB1+

PharmaJet[®]



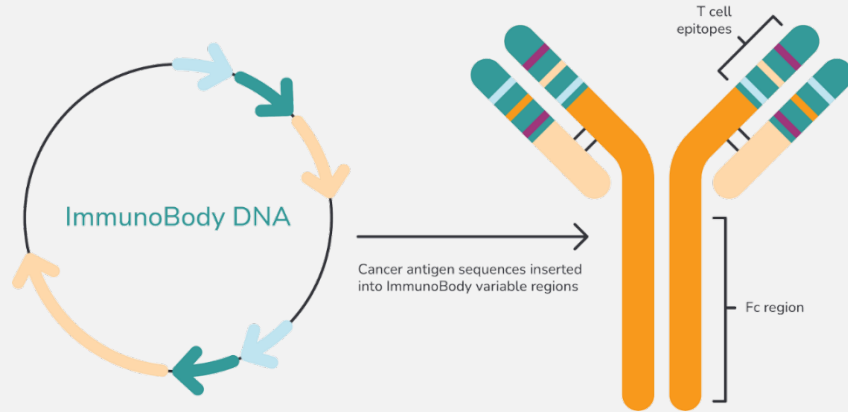
Stratis[®] IM

Needle-free Injection System for 0.5 ml Intramuscular

- ✓ **No needle**
 - ✓ **Spring-powered**
 - ✓ **No external power source**
- Deliver a spring-powered injection in 0.1 seconds by means of a narrow stream of fluid that penetrates the skin with a precise dose and depth

- ▶ Stratis[®] has shown effective uptake of the DNA vaccine
- ▶ Widely accepted and favored by patients and clinicians throughout the SCOPE Study
- ▶ Stratis[®] has U.S. FDA 510(k) marketing clearance, CE Mark, and World Health Organization prequalification to deliver medications and vaccines intramuscularly or subcutaneously
- ▶ License agreement has been completed in preparation for the Phase 2/3 randomized registrational trial planned for 2025

SCIB1/iSCIB1+ are Dual Action Tumour Targeted DNA Cancer Vaccines with a Favorable Safety Profile



TUMOUR TARGETED

Incorporates specific epitopes from gp100 and TRP-2 proteins identified from T cells of patients who achieved spontaneous recovery from melanoma skin cancers

DUAL ACTION

Direct and indirect Fc targeting of activated dendritic cells initiates direct and cross-presentation of epitopes to T cells resulting in higher T cell avidity of up to 100-fold increased potency and increased number of T cells to tumour epitopes

LOW TOXICITY

Favorable safety and tolerability alone or when added to checkpoint inhibitor treatment with potent vaccine specific T cell responses

SCIB1 is being developed in cutaneous melanoma with compelling efficacy data, outperforming current market benchmarks

- ▶ Post resection patients achieve 95% disease-free survival (DFS) at 12 months and 88% at 5 years, unresected patients currently achieve 60% stable disease
- ▶ **SCIB1 in combination with CPI from Phase 2 SCOPE trial reported positive data with an ORR of 85% exceeding the 70% target set for continuation of the study**

iSCIB1+ second generation technology offers improved product

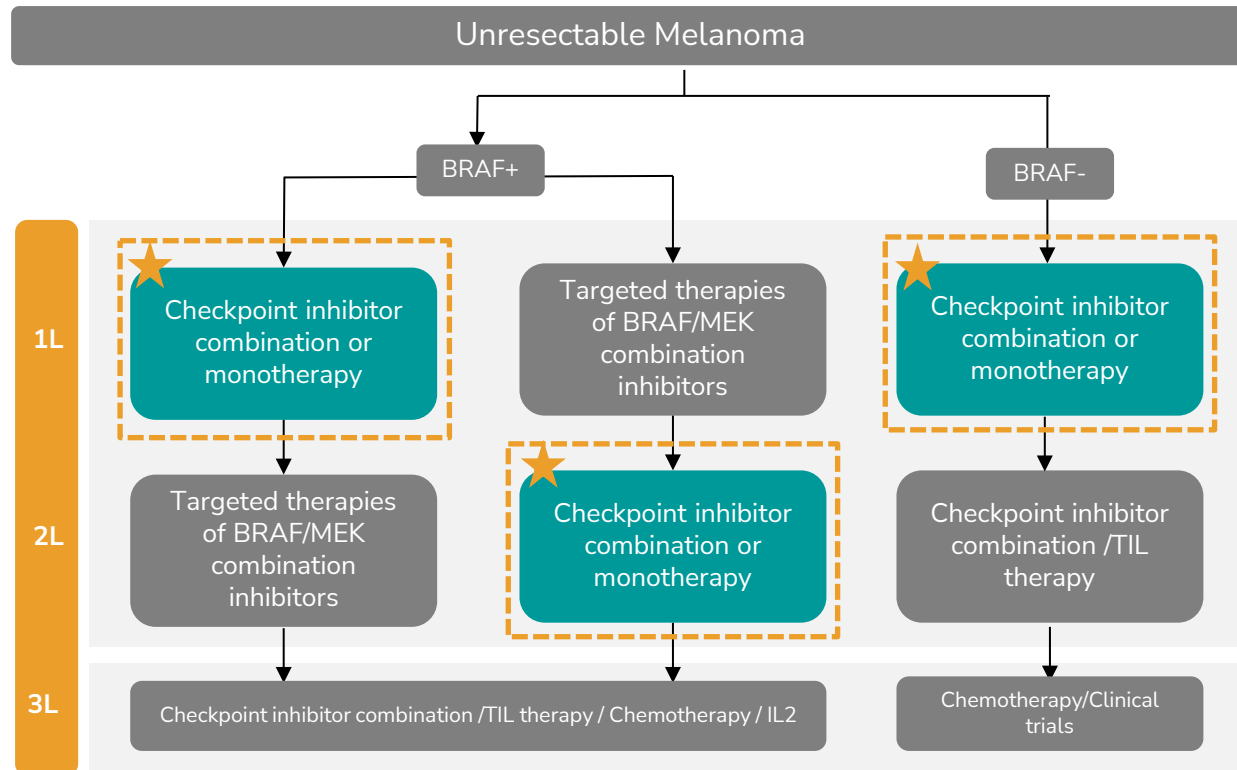
- ▶ No HLA screening, can access 100% of the addressable patient population
- ▶ AvidiMab® modification increases potency and gives 15 years extended patent protection
- ▶ **iSCIB1+ cohort recruitment underway, data expected H1 2025 to prove non-futility and patient benefit**



SCIB1	Amino acids	HLA/DR	iSCIB1+
✓	H1: gp100 173-190	A2/DR7/DR53/DQ6	✓
✓	H2: TRP2 180-188	A2	✓
✓	H3: gp100 471-492	DP4/A1/B35	✓
✓	L1: gp100 44-59	DR4	✓
	L2: TRP2 177-205	A2/DP4/A31/A33/A3	✓
	L3: TRP2 60-91	DR3/B35/B44	✓

Treatment landscape for unresectable melanoma

SCIB1/ iSCIB1+ is used alongside double checkpoint inhibitor nivolumab and ipilimumab



- ▶ Phase II SCOPE trial, SCIB1/ iSCIB1+ is used alongside double checkpoint inhibitor nivolumab and ipilimumab as a treatment for unresectable stage III/IV melanoma
- ▶ Will set the potential new benchmark for first-line unresectable melanoma
- ▶ Addressable population of 60k¹ per annum
- ▶ Two cancer vaccines are also in 1L unresectable melanoma combined with PD-1 only – IO Biotech & BioNTech
- ▶ The Moderna personalized vaccine is in resectable melanoma and currently in a Phase 3 approval trial due to complete by 2029

SCOPE Study Design

Eligibility

- ▶ Histologically confirmed unresectable AJCC stage III or stage IV melanoma
- ▶ No prior treatment for advanced disease
- ▶ Suitable for treatment with ipilimumab and nivolumab with measurable disease
- ▶ Simon stage 1 >8/15 ORR
- ▶ Simon stage 2 >27/43 ORR

Cohorts

- Three cohorts across 16 sites in the UK:
- ▶ Cohort 1: SCIB1 + SoC nivolumab and ipilimumab (n=36)
 - ▶ Cohort 2: SCIB1 + SoC pembrolizumab (n=8)
 - ▶ Cohort 3: iSCIB1 + SoC nivolumab and ipilimumab (n=27)

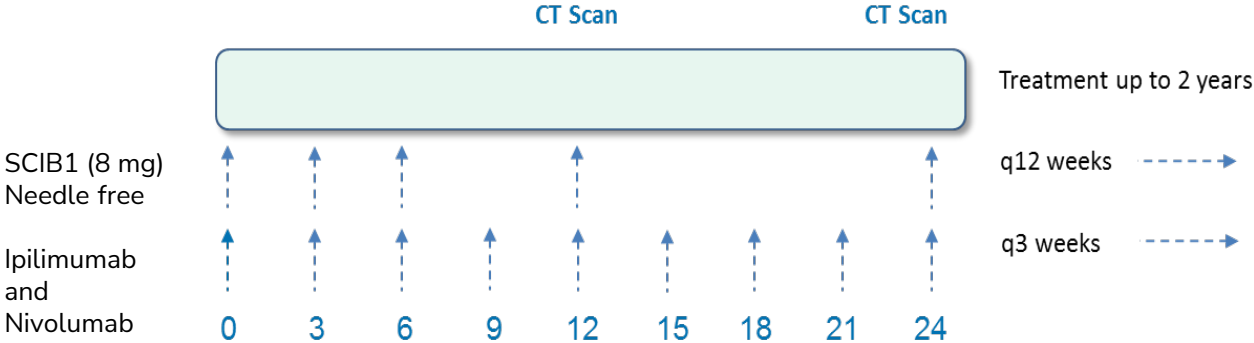
Endpoints

Primary Endpoints

- ▶ ORR

Secondary Endpoints

- ▶ DoR
- ▶ PFS
- ▶ OS
- ▶ Safety and tolerability

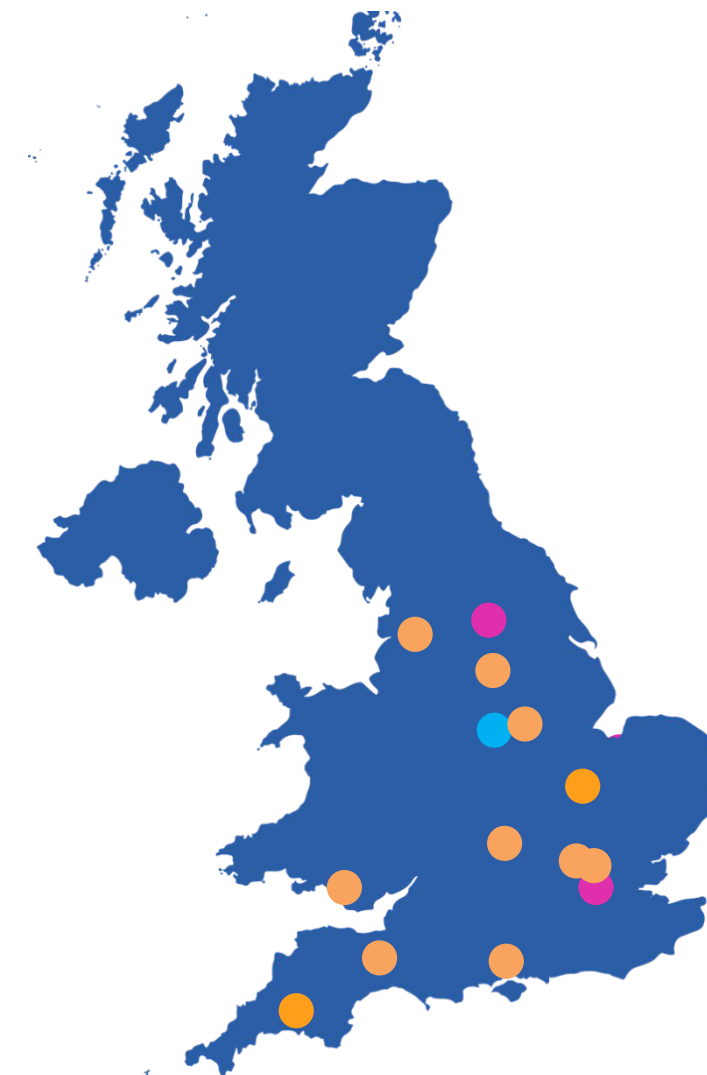


Assumptions

- ▶ Response rate to ipilimumab and nivolumab = 50%
- ▶ Response rate of interest for combination = 70%

SCOPE Study Participating Sites

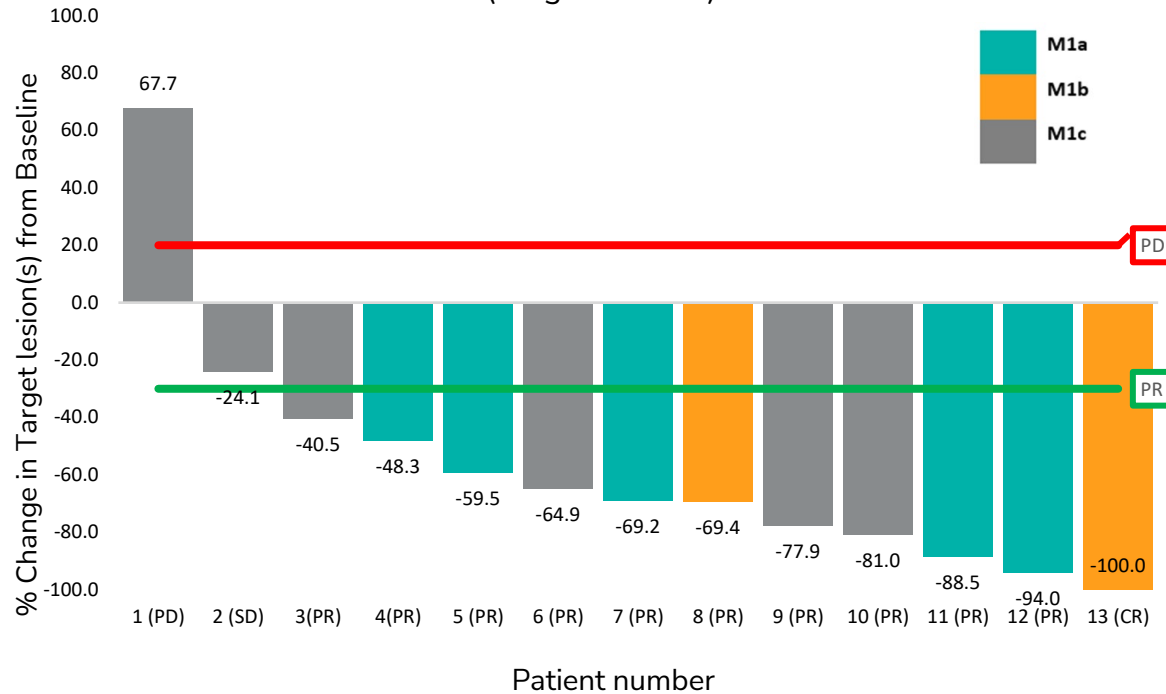
Participating Sites		Principal Investigator
01	Nottingham City Hospital	Professor Poulam Patel
02	Velindre Cancer Centre, Cardiff	Dr Satish Kumar
03	Mount Vernon Cancer Centre, Northwood	Dr Heather Shaw
04	Churchill Hospital, Oxford	Dr Miranda Payne
05	Royal Preston Hospital	Dr Kellati Prasad
06	Weston Park Hospital, Sheffield	Professor Sarah Danson
07	Musgrove Park Hospital, Taunton	Dr Clare Barlow
08	Derriford Hospital, Plymouth	Dr Martin Highley
09	Royal Free Hospital	Dr Amna Sheri
10	Guy's Hospital	Dr Amanda Fitzpatrick
11	Southampton General Hospital	Prof Ioannis Karydis
12	Royal Derby Hospital (PIC)	Dr Kate Shankland
13	St James' University Hospital, Leeds	Dr Maria Marples
14	Royal Marsden Hospital	Dr Kate Young
15	The Christie	Dr Rebecca Lee
16	Addenbrooke's Hospital, Cambridge	Dr Pippa corrie



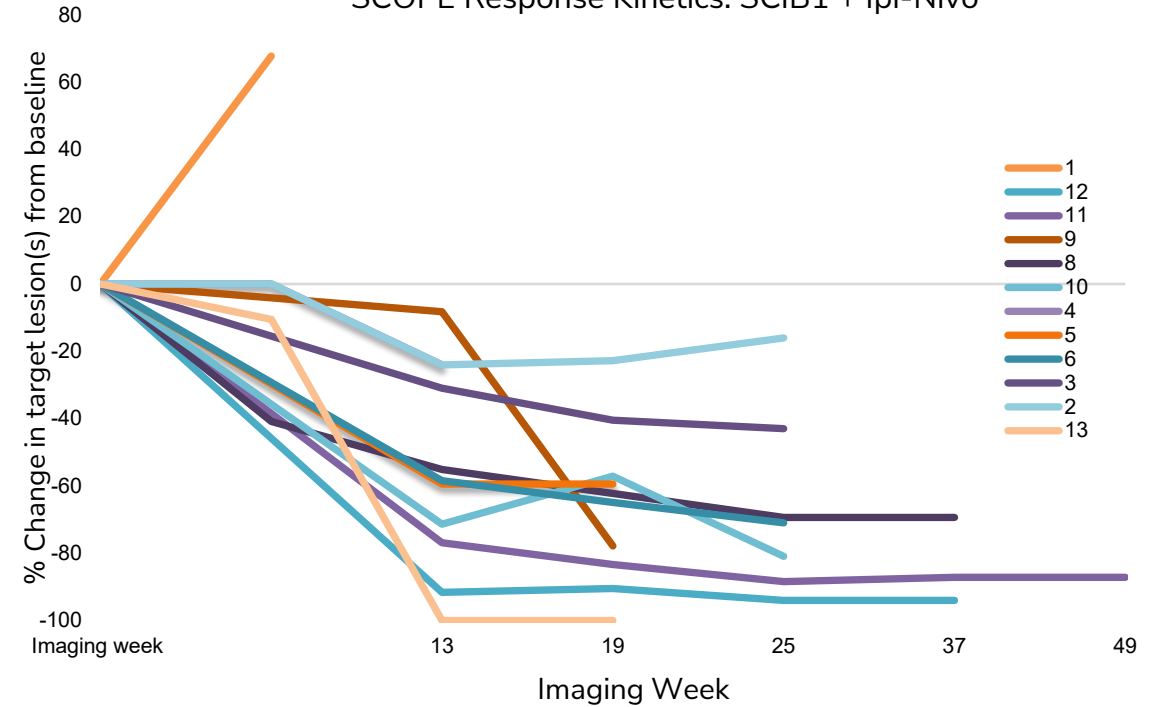
SCOPE Study: SCIB1 Simon Stage 1 Results Cohort 1



SCOPE Study Cohort 1: Waterfall Plot Best Tumour Response (Target Lesions)



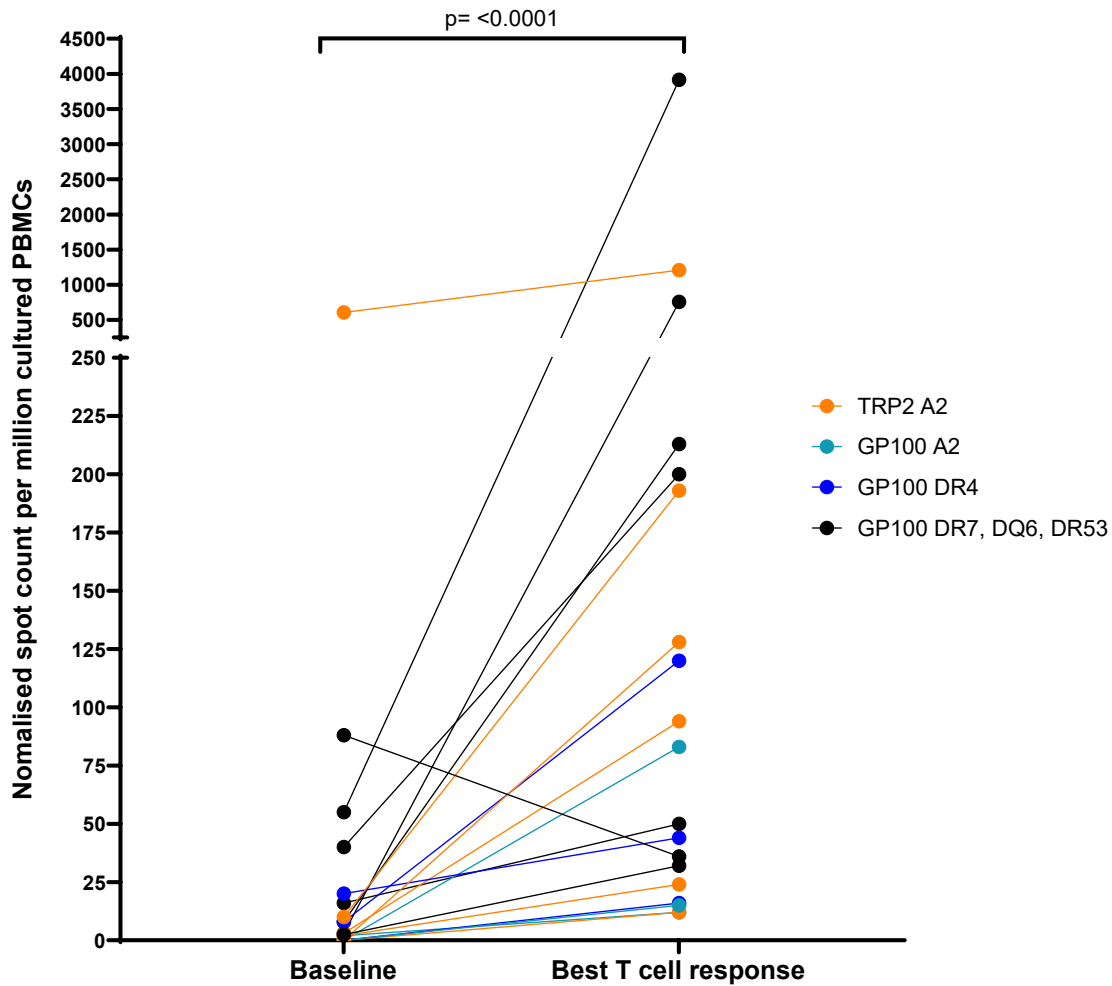
SCOPE Response Kinetics: SCIB1 + Ipi-Nivo



N=13	
ORR (95% CI)*	85%
Complete response (CR)	1
Partial response (PR)	10
Stable disease (SD)	1
Progressive disease (PD)	1

- ▶ Confirmed response in 11/13 patients
- ▶ 1 confirmed CR
- ▶ 36 patients immunised

SCOPE Patients Demonstrate Potent Vaccine Specific T Cell Responses



Cohort 1 patients

- ▶ Best T cell response for any peptide at any time point post vaccination plotted against corresponding response at baseline
- ▶ All data sets have passed the acceptance criteria
- ▶ Positive responses determined using distribution-free resampling (DFR) test
- ▶ 19 patients in Cohort 1 who have received 3 or more SCIB1 doses

Dose escalation and Safety

- ▶ Monotherapy tested across 4 tumour types
- ▶ Low and high dose tested as monotherapy
- ▶ Low and high dose tested in combination with PD-1
- ▶ Good safety and stable disease
- ▶ No dose limiting toxicities observed

Dose expansion

- ▶ Monotherapy across 4 tumour types
- ▶ Combination therapy in two tumour types
- ▶ Combination therapy in neoadjuvant tumour
- ▶ **Untreated renal cell carcinoma (RCC) patients in combination with doublet CPI therapy**

Endpoints

Primary Endpoints

- ▶ ORR

Secondary Endpoints

- ▶ DoR
- ▶ PFS
- ▶ OS
- ▶ Safety and tolerability

- ▶ Early data from patients receiving Modi-1 as a monotherapy showed good T cell responses, safety and stable disease
- ▶ To build on the results seen in the SCOPE trial, we are investigating Modi-1 in advanced renal cell carcinoma (RCC) in the first line setting, where double checkpoint inhibitor is standard of care
- ▶ A cohort was approved in **May 2024**, which will recruit 44 previously untreated RCC patients who will receive the Modi-1 cancer vaccine with CPIs. We believe this will demonstrate that Modi-1 peptides improve the ORR and further demonstrate that double checkpoints are highly effective when synergising with targeted vaccines
- ▶ Four patients dosed to date; further clinical data **expected in H1 2025**

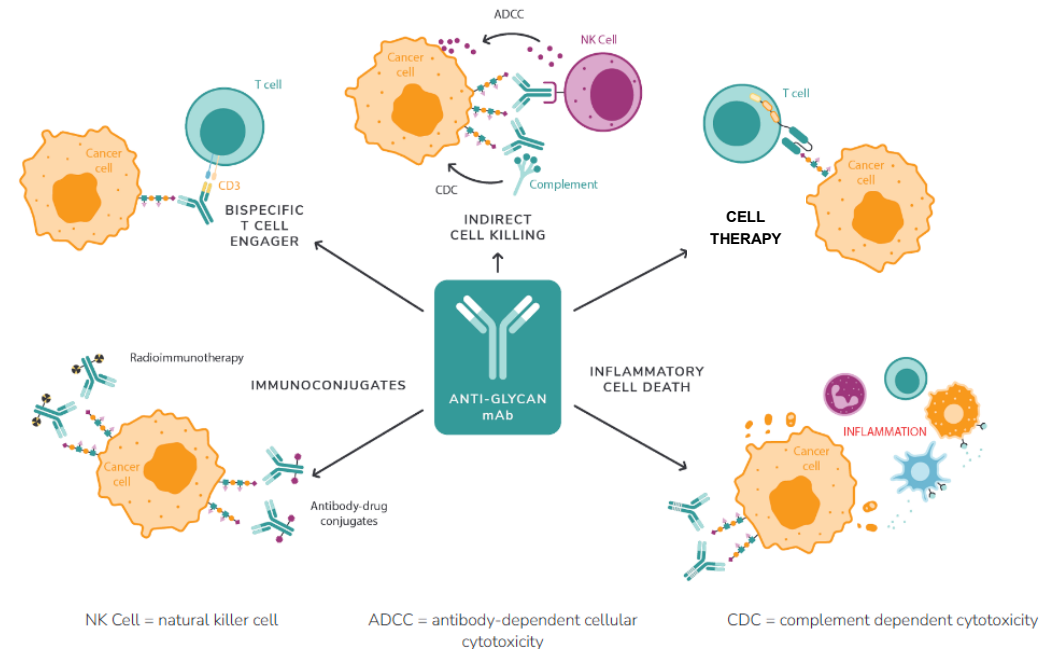
Portfolio of Patent Protected Anti-Glycan Antibodies with Therapeutic Development Potential

Targeting highly specific and highly differentiated glycans preferentially expressed on tumours

SC129	<ul style="list-style-type: none"> • Genmab licensed for ADC/TCB/radioimmunotherapy • Sialyl-di-Lewis^a • Pancreatic cancer
SC134 ★	<ul style="list-style-type: none"> • T Cell engager is the lead target • Fucosyl GM1 • Small cell lung cancer
SC2811	<ul style="list-style-type: none"> • SSEA4 • Any solid tumour
SC27	<ul style="list-style-type: none"> • Lewis^y • Ovarian cancer

One antibody is under exclusive evaluation for ADC/TCB/radioimmunotherapy

Deliver differentiated products for unmet markets



NK cell = natural killer cell; ADCC = antibody-dependent cellular cytotoxicity; CDC = complement-dependent cytotoxicity

Value to partners: novel targets that can be developed into multiple products supported by strong pre-clinical data

Value to Scancell: revenue generation through multiple licensing opportunities, develop in-house therapeutic product

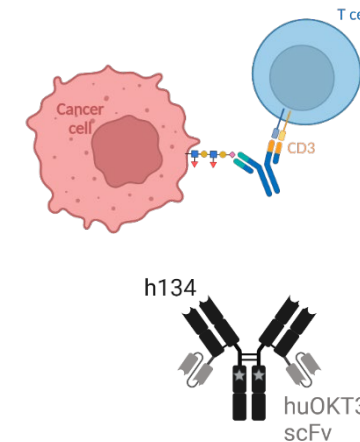
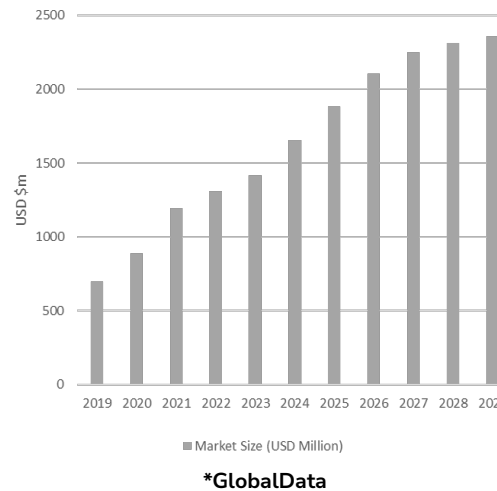
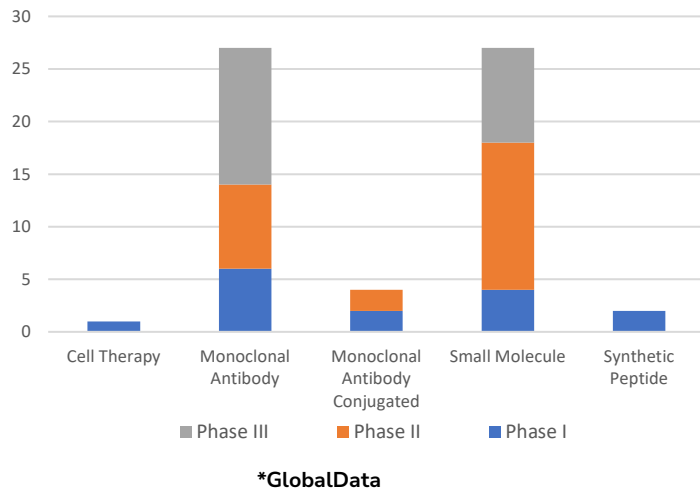
Opportunity for SC134 in SCLC



Small Cell Lung Cancer

- 250,000 patient population
- 75% diagnosed with aggressive form of the disease
- Poor prognosis with 5-year survival of >18%

- Currently very few 1L treatment options for SCLC patients
- Clinically validated target (BMS-986012) due to start Phase 3 study



MOLECULAR CANCER THERAPEUTICS

RESEARCH ARTICLE | AUGUST 26, 2024

SC134-TCB targeting fucosyl-GM1, a T cell engaging antibody with potent anti-tumour activity in preclinical small-cell lung cancer models

Abstract
Supplementary data

Check for updates

Author & article information
Mol Cancer Ther 2024; 23(8):1500-1510. DOI: 10.1158/1538-7445.2024.01500

Split Screen View PDF Share Tools Versions

Abstract

Small-cell lung cancer (SCLC) is an aggressive disease with limited treatment options. Fucosyl-GM1 (FucGM1) is a glycolipid overexpressed in the majority of SCLC tumours, but virtually absent from normal healthy tissues. Here, we validate a FucGM1-targeting T cell redirecting bispecific antibody (TCB) for the treatment of SCLC. Over 80% of SCLC patient-derived xenograft (PDX) tissues expressed FucGM1, whilst only three normal human tissues (pituitary, thymus and skin) expressed low and focal FucGM1. A FucGM1-targeting TCB (SC134-TCB), based on the FucGM1-binding humanised h134 antibody epitope, FucGM1 glycolipid and SCLC cell surface binding. SC134-TCB showed potent ex vivo killing of SCLC cell lines with donor-dependent EC50 ranging from 7.2 pM to 211 pM, effectively activating T cells with proliferative efficiency, consistent with target-dependent cytokine production such as interferon gamma, interleukin-2 and tumour necrosis factor alpha and robust proliferation of both CD4 and CD8 T cells. The ex vivo SC134-TCB tumour controlling activity translated into an effective in vivo anti-DM579 tumour therapy, resulting in 100% tumour-free survival in a human PBMC adoptive setting and 40% overall survival (55% tumour growth inhibition) with systemically administered human PBMC. Combination treatment with

ADC and monoclonal antibody approaches dominate clinical development. First T cell engager to be approved in solid tumors is tarlatamab, setting a benchmark for future therapies

Global SCLC (8MM) forecast to reach \$23bn by 2029. Modest late-phase pipeline for SCLC to boost market with Amgen's bispecific T-cell engager (BiTE) tarlatamab and Daiichi's antibody-drug conjugate (ADC) ifinatamab deruxtecan

SC134 is a Highly Effective T Cell Engager for SCLC, supported by peer-reviewed publication
Exploring partnering opportunities with strong commercial interest

Timelines and Outlook



Scancell Key Financial Highlights



Consolidated Statement of Comprehensive Income (£m)	12 months 30 April 2024	12 months 30 April 2023
Revenue	-	5.3m
Gross Profit	-	4.7m
Development Expenses	(12.9m)	(11.6m)
Administrative Expenses	(5.4m)	(5.0m)
Operating Loss	(18.3m)	(11.9m)
Finance & Other Income / (Expense)	9.2m	(2.4m)
Taxation	3.2m	2.4m
Loss for Year	(5.9m)	(11.9m)

Consolidated Position of Financial Position (£m)	12 months 30 April 2024	12 months 30 April 2023 ¹
Non-Current Assets	1.7m	2.2m
Cash & Cash Equivalents	14.8m	19.9m
Other Current Assets	7.1m	4.8m
Total Assets	23.6m	26.9m
CLNs & Derivative Liabilities	(23.1m)	(32.5m)
Other Liabilities	(4.0m)	(4.0m)
Net (Liabilities) / Assets	(3.5m)	(9.6m)

- ▶ Revenue in FY23 relates to SC129 upfront. Further revenue opportunities as with SC129 development on track & antibodies under evaluation.
- ▶ Development Expenses includes in-house clinical, manufacturing and research costs focused on development on SCIB1, iSCIB1+ and Modi-1 including readiness for next stages of development.
- ▶ Cash & Cash Equivalents at 14.8m, enhanced post year-end with FY23 R&D tax credit of £2.9m & \$1m exclusivity payment for antibody.
- ▶ Financing in late 2023 raise £11.9m spent as planned including iSCIB1+ cohort & P2/3 readiness for next stages of development & Modi-1
- ▶ Convertible Loans Notes maturity dates extended by 2 years with interest deferred and accrued resulting in net positive cash impact.
- ▶ Cash runway to Q3 2025 beyond clinical milestones.

Shares Outstanding (Basic) at 31 August 2024 928,979,977

1. Restated; Full Financial Statements available on Company Website

Strong pipeline of news flow



		2024	2025	2026+
VACCINES	SCIB1/ iSCIB1+ SCOPE	SCIB1 & doublet CPI 27/43 responses iSCIB1+ doublet CPI initiation	iSCIB1+ doublet CPI 27/43 responses Start Phase 2/3 registration study ¹	Results of Phase 2 randomised trial ¹
	Modi-1 ModiFY	Modi-1 CPI expansion	Early clinical results	Phase 2/3 ¹
ANTIBODIES	134 TCB			Phase 1/2 ¹
	GlyMab [®] / AvidiMab [®]	← Licensing →		

CPI: Checkpoint inhibitor
 ORR: Overall response rate
 PFS: Progression-free survival

¹ Subject to further out-licensing, partnering and/or further financing

Near term clinical milestones and value drivers

SCOPE Study

- Full cohort data with SCIB1 and iSCIB1+ in Q4 2024 and H1 2025
- Phase 2/3 seamless registration trial with SCIB1 or iSCIB1+ to begin in 2025

ModiFY

- ModiFY study data in RCC in combination with checkpoint inhibitors expected in H1 2025

Antibodies & Other

- Out-licensing discussions for the GlyMab[®] and AvidiMab[®] platforms
- Partnering options continually assessed to drive further value in all assets

Thank you

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