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Scancell Holdings Plc
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Scancell updated Phase 2 data shows continued improvement in progression free survival with iSCIB1+ in patients with first line advanced melanoma

Progression free survival (PFS) of 74% at 16 months compares favourably to standard of care PFS of 50% at 11.5 months [1]

Strong PFS consistent across key subgroups

Reaffirms selection of iSCIB1+ and target HLA population for late-stage development

Early overall survival (OS) data, most advanced for SCIB1, showing a 14% improvement at 26 months over SoC[1]

In advanced planning for registrational trials with positive scientific advice from regulators

To hold late-breaking oral presentation on SCOPE trial at ESMO IO conference

Investor webinar on Thursday 11th December 2025 at 2.00pm GMT

Scancell Holdings plc (AIM: SCLP), the developer of active immunotherapies to treat cancer, announces updated positive data from the SCOPE Phase 2 trial of iSCIB1+ in combination with ipilimumab and nivolumab, current standard of care (SoC). A late-breaking abstract on the data has been released, and an additional poster presentation will be made during an oral session at the ESMO Immuno-Oncology Congress 2025 (ESMO IO) conference on 11th December 2025.

Results from SCOPE to date have enabled Scancell to select Immunobody iSCIB1+, administered needle-free intramuscularly, for further development in patients with selected human leukocyte antigen (HLA) alleles ("the target population"), representing 80% of melanoma patients. This profile is reflected within Cohort 3 of the SCOPE trial.

Updated data in this cohort show progression free survival (PFS) was 74% at 16 months in the target population. This compares favourably to PFS reported with ipilimumab plus nivolumab alone of 50% at 11.5 months[1]. The favourable PFS remains consistent across key subgroups analysed including PD-L1 low, BRAF Wildtype and prior checkpoint inhibitor exposure, who might be expected to have worse outcomes. Cohort 3 comprised a total of 50 patients of which 39 were in the target HLA population, 10 outside the target HLA population and one was non-evaluable due to active brain metastases. Data in this cohort from the non-target population support the use of HLA as a biomarker for a registrational trial, with PFS of 20% at 14 months and overall response rate of 20%, albeit in a small number of patients.

Dr Heather Shaw, lead for the Medical Oncology Skin Cancer Service at University College London Hospital, London and principal investigator of the SCOPE trial at Mount Vernon Cancer Centre, said: "The prolonged progression free survival demonstrates iSCIB1+ in combination with checkpoint inhibitors has potential to redefine standard of care. This therapy combination increases the number of advanced melanoma patients who would benefit and improves the duration of their clinical response versus equivalent timepoints with checkpoint inhibition alone, thus representing an important step forward for patient outcomes."

Overall response rate for the target population in Cohort 3 was 56%, with a disease control rate of 79%. iSCIB1+ specific T cell responses correlated positively with clinical benefit, seen in 72% of patients mounting a T-cell response to both GP100 and TRP2 epitopes, thereby overcoming immune escape. A memory T-cell response phenotype was also characterised in these patients. Early overall survival (OS) data, most advanced for SCIB1, shows a 14% improvement at 26 months over SoC.

Dr Nermeen Varawalla, Chief Medical Officer of Scancell, said: "iSCIB1+, in combination with checkpoint inhibitors, is showing a significant 24% improvement in PFS over standard of care and more efficacy than the first generation SCIB1. This provides additional confidence in the Immunobody® being taken forward towards registrational trials. The translational data backing these clinical outcomes is also compelling, showing that iSCIB1+ drives a powerful durable T-cell response."

The Company has held positive discussions with the U.S Food and Drug Administration (US FDA) and other regulatory agencies. The feedback received to date supports our plans to move to Phase 3 registrational development with iSCIB1+ with alignment on trial design, dose, manufacturing and progression free survival as the expected registrational endpoint. The Company will continue active partnering, whilst assessing options to finance the next stage of development.

Dr Phil L'Huillier, CEO of Scancell, said: "These results give further momentum to our advanced planning for late-stage clinical development. We are continuing our positive discussions with the US FDA and other regulators, with feedback supporting our plans to move iSCIB1+ to late-stage development in 2026. The positive and growing durability of responses with iSCIB1+ delivered intramuscularly demonstrate that this method of administration is the optimal form to be investigated in late-stage development, and as a result we have decided not to continue with Cohort 4, with iSCIB1+ delivered intradermally. In parallel, we are also in active discussions with potential partners as we assess the optimal options to finance this next stage."

Scancell will host a presentation on the SCOPE data, followed by a Q&A with management, on 11 December at 14:00 GMT. Please click here to register for the call.

Details of the ESMO IO oral and poster presentation

Title: SCOPE, phase 2 clinical trial with off-the-shelf DNA plasmid vaccine in first line advanced melanoma with check point inhibition

Presenter: Professor Heather Shaw, Medical Oncology, Mount Vernon Cancer Centre, University College London

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Time: Thursday December 11, 11:50 GMT

Location: 2025 ESMO Immuno-Oncology Annual Congress, Queen Elizabeth II Conference Centre, London

	Cohort 1	Cohort 3	Cohort 3	Combined Cohorts	Check
Product	SCIB1	iSCIB1+	iSCIB1+	SCIB1 & iSCIB1+	
HLA population	Target A2	Target A2, A3, A31, Bw4, B35 and B44	Non Target A1	Target A2, A3, A31, Bw4, B35 and B44	
N=	41	39	10	80	
Overall Survival (OS)	77% 26 months	Too early	Too early	Too early	26
Progression Free Survival (PFS)	55% 26 months	74% 16 months	20% 14 months	60% 26 months	50% 11.5
DCR	83%	79%	40%	81%	
ORR	63%	56%	20%	60%	50%
Non-evaluable	2	1	-	-	

Note: Combined cohorts illustrative of larger target HLA population. Cohort 2 was halted previously due to a change in standard of care. Cohort 4 too early for meaningful PFS analysis.

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR).

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SCOPE (ClinicalTrials.gov: NCT04079166) is a Phase 2, UK multi-centre open-label study investigating SCIB1/iSCIB1+ in combination with checkpoint inhibitors in late-stage melanoma and will enrol more than 140 patients across four cohorts. Its aim is to evaluate the efficacy, safety and durability of SCIB1 or iSCIB1+ DNA Immunobody® therapies when given to patients in combination with SoC checkpoint inhibitors in stage IIIB/IV unresectable metastatic melanoma, and to define the parameters to design a Phase 3 randomised registration trial.

iSCIB1+ incorporates specific epitopes from the proteins gp100 and TRP-2 which play key roles in the production of melanin in the skin and were identified from T cells of patients who achieved spontaneous recovery from melanoma skin cancers. iSCIB1+ was designed to work in HLA alleles A1, A2, A3, A31, A33, Bw4, B35, and B44, representing close to 100% of late-stage melanoma patients. The Phase 2 study has confirmed iSCIB1+ combination with SoC is efficacious in patients with A2, A3, A31, Bw4, B35 and B44 epitopes, representing 80% of the melanoma patients, though the combination did not stimulate a clinical response in patients with A1 and other HLA types with no matched epitopes. The selected HLA alleles of A2, A3, A31, Bw4, B35 and B44 are thus defined as the target HLA population. This HLA selection can be used as a tool to select for responders in future clinical development.

Scancell (LSE:SCLP; www.scancell.co.uk) is a clinical stage biotechnology company developing targeted off-the-shelf active immunotherapies, to generate safe and long-lasting tumour-specific immunity for a cancer-free future. iSCIB1+, the lead product from their DNA ImmunoBody® platform has demonstrated safe, durable and clinically meaningful benefit as a monotherapy as well as additional benefit when combined with checkpoint therapies in an ongoing Phase 2 trial in melanoma. Modi-1, the lead peptide immunotherapy from their Moditope® platform, is being investigated in a Phase 2 study in a broad range of solid tumours. In addition, Scancell's wholly owned subsidiary, GlyMab Therapeutics Ltd., has been established with the intention to hold and develop an exciting early-stage pipeline of high affinity GlyMab® antibodies targeting tumour specific glycans, two of which already have been licensed and are being developed by Genmab A/S, an international biotechnology company and global leader in the antibody therapeutics space.

Progression free survival: The length of time during and after treatment that a patient lives with a disease without it worsening.

Overall survival: The length of time from diagnosis or treatment for a disease, that patients are still alive.

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[1] Ipilimumab and Nivolumab in Checkmate 067

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