RNS Number : 5721G
Scancell Holdings Plc
07 November 2025

7 November 2025

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Scancell holds oral presentation of positive Phase 2 data on Immunobody® iSCIB1+ in late-stage melanoma at SITC 2025

Data from SCOPE trial show a potential new benchmark in efficacy, durability, immune responses and safety

Progression-free survival (PFS) for iSCIB1+ in target population at 11 months is 78%, compared with historic 12 months PFS of 46% with doublet checkpoint therapy of ipilimumab and nivolumab

Development plans for iSCIB1+ accelerated including regulatory and partnering discussions, with randomised studies on path to registration expected to start in 2026

Scancell Holdings plc (AIM: SCLP), the developer of Immunobody® and Moditope® active immunotherapies to treat cancer, announces the presentation of positive data from the ongoing Phase 2 SCOPE trial of its iSCIB1+ Immunobody® DNA active immunotherapy, in combination with checkpoint inhibitors in patients with advanced unresectable melanoma, at the Society for Immunotherapy of Cancer (SITC) 40th Anniversary Annual Meeting in National Harbor, MD, USA.

The data, first reported in July and now outlined in an oral presentation, show that iSCIB1+ is a potential new benchmark for treatment of patients with late-stage melanoma in terms of efficacy, durability, immune responses and safety. SCOPE results to date show progression-free survival (PFS) for iSCIB1+ in the target human leukocyte antigen (HLA) population at 11 months is 78%, compared with the historic 12-month PFS of 46% reported by doublet checkpoint therapy of ipilimumab and nivolumab.[1]

Dr Nermeen Varawalla, Chief Medical Officer of Scancell, said: *"The data from SCOPE so far indicate that iSCIB1+ has groundbreaking potential to deliver meaningful clinical benefits to patients. It has been shown to enhance response rates, disease control, progression-free survival and immune activation, combined with a robust safety profile that allows integration with standard of care without added toxicity. This positions iSCIB1+ as a transformative option for patients with metastatic melanoma and opens possibilities for earlier-stage, resectable disease in neoadjuvant or adjuvant settings, and we are looking forward to moving this exciting ImmunoBody® into randomised studies, on the path to registration, in 2026."*

Combined data for the defined HLA target population across Cohorts 1 and 3 shows 22-month PFS of 69%, representing a meaningful improvement over historic doublet checkpoint therapy. The overall response rate (ORR) and disease control rate (DCR) for SCIB1 and iSCIB1+ also demonstrate superiority whether combined with doublet checkpoint or single checkpoint therapy, and data from more than 100 patients across the trial show a favourable safety profile.

Based on these data, iSCIB1+ has been selected for future development expanding the addressable patients to around 80% of late-stage melanoma patients and with longer patent life. Development plans are now accelerated including regulatory and partnering discussions. Randomised studies on the path to registration are anticipated to begin in 2026.

Details of the presentation

Title: SCOPE, an open label phase 2 parallel multi cohort clinical trial evaluating an off-the-shelf DNA plasmid vaccine in first line advanced melanoma combined with check point blockade - interim read-out.

Abstract Number: 1325

Session: Clinical Oral Abstract Session 2

Date and time: Saturday, November 8, 2025, 1:45 PM ET

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 inform the design of a Phase 2b/3 randomised controlled registration trial.

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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.

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[1] Ipilimumab and Nivolumab in Checkmate 067

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