19 September 2023

Scancell Holdings plc
("Scancell" or the "Company")

Scancell announces positive data from the first stage in its Phase 2 SCOPE trial with SCIB1 cancer vaccine delivered by needle free injection for advanced melanoma

Key Highlights

- SCOPE trial surpasses its first milestone with an 82% response rate
- To our knowledge no other combination has achieved this response rate with doublet checkpoint inhibitors in unresectable metastatic melanoma
- Analyst and Investor webcast today at 1pm, full details below

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, announces positive data from the first stage in its Phase 2 SCOPE trial, investigating SCIB1 in combination with checkpoint inhibitors (CPIs) in advanced melanoma. Initial data from 11 patients showed an 82% objective response rate (ORR) to treatment, which is better than 70% ORR that the trial was configured to show.

The Phase 2 SCOPE trial was designed to determine if the ORR in patients with unresectable metastatic melanoma could be improved in combination with CPIs. The concept is that the vaccine induces new, or boosts existing, immune responses which are subsequently protected in the tumour environment by the CPIs. During the first stage of the SCOPE trial patients received SCIB1 via a needle-free device in combination with the most efficacious treatment currently available, namely the CPIs nivolumab and ipilimumab. The first milestone in the SCOPE trial was to achieve responses in more than 8 out of 15 patients which would suggest that SCIB1 in combination with doublet CPI therapy might meaningfully improve current outcomes for these patients. 16 stage IV metastatic patients have received this combination. To date, 11 of these study patients have reached 13 weeks and been evaluated at radiological imaging and nine have already shown an objective response, equating to an ORR of 82% with no increase in toxicity. At this time point the reduction in tumour volume was 31%-94%. Four patients reaching the 25 weeks imaging evaluation and two reaching the 37 weeks evaluation have shown a 69%-94% and a 87%-94% reduction in total tumour burden, respectively. This compares to an ORR of 50% reported in patients just receiving this doublet CPI therapy in the real world setting with a progression free survival time of 11.5 months.

Prof Poulam Patel, Chief Investigator, added: *"These results, if confirmed in a larger cohort, will be a significant improvement on what patients can expect from available treatment today. We look forward to continuing the second stage of the study and reporting further data in due course."*

Prof Lindy Durrant, Chief Executive Officer of Scancell, commented: *"We are excited by these highly impressive results for SCIB1 combined with the doublet CPI therapy. We thought results from the Phase 1/2 trial evaluating SCIB1 as a monotherapy were positive but results from this combination are even more meaningful. Previous studies indicated that a response rate of 50% was the best that could be achieved in the real world setting for patients with unresectable metastatic melanoma, as no other combination had improved on the response rates for doublet CPI alone. Confirmation of this data in a larger cohort could make a significant impact on melanoma patient survival, especially as melanoma is now one of the most common cancers in young women."*

The SCOPE trial has now successfully transitioned into the second stage, which will recruit a further 27 patients (for a total of 43). The aim is to achieve at least 18 further responses (i.e., 27 responses in total) which would statistically demonstrate that SCIB1, in combination with doublet therapy, exceeds currently achievable ORRs. Recruitment is expected to be complete by the end of 2023 with data available in H1 2024. Based upon the first 11 patients there is a greater than 90% probability that the second phase will also be successful.

An amendment to the current trial protocol, to include a new parallel cohort with the double CPIs with iSCIB1+, has been submitted to the Medicines and Healthcare products Regulatory Agency (MHRA). iSCIB1+ has a number of additional competitive advantages to SCIB1, including potentially increased potency due to modifications to the product

using Scancell's propriety AvidiMab® platform, and an extended patent life. iSCIB1+ is also able to be used by a broader patient population because it incorporates more melanoma-specific epitopes. It is anticipated that data from this cohort will read out in the first half of 2024.

If validated in the second stage of the SCOPE trial this will provide confidence to initiate a randomised phase 2/3 adapted registration programme in patients with unresectable melanoma which represents a potential $1.5 billion per annum market. The Phase 2 part of the adapted trial should take 18 months and will likely generate significant partner interest.

In addition to SCIB1, Scancell expects significant results from its other programmes in 2024 including top-line Modi-1 CPI combination data and attractive out-licensing opportunities from the GlyMab® and AvidiMab® platforms.

Analyst and investor webcast
Professor Lindy Durrant, Chief Executive Officer, and Sath Nirmalananthan, Chief Financial Officer, will host a live webcast and Q&A session for analysts and investors at 13:00 BST / 8:00 ET. If you would like to join the webcast, please follow this link:

Issuer Services | London Stock Exchange | SCANCELL HOLDINGS PLC (lsegissuerservices.com)

A replay of the webcast will be made available shortly afterwards.

Please contact ICR Consilium for further details.

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

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About the SCOPE Phase 2 clinical trial

SCOPE is an open label, multicohort, multicentre, Phase 2 study of SCIB1 in patients with advanced unresectable melanoma receiving either nivolumab with ipilimumab or pembrolizumab. SCIB1 is a deoxyribonucleic acid (DNA) plasmid vaccine encoding two CD8 epitopes from the melanoma antigens tyrosinase-related protein-2 and glycoprotein 100 (gp100), plus two CD4 epitopes from gp100.

The purpose of the study is to determine whether the addition of SCIB1 to standard of care checkpoint inhibitors can improve the objective response rate (ORR) of patients with advanced melanoma relative to the checkpoint inhibitors alone. The ORR is defined as the proportion of patients with a complete or partial response at any time after the start of treatment.

During the first stage of the SCOPE trial reported here, patients received SCIB1 in combination with the best treatment currently available, namely the CPIs nivolumab and ipilimumab. The First Stage milestone was protocolled to demonstrate at least a 70% ORR with an 80% power ie at least 8/15 patients responding, assessed by radiological imaging.
Further information relating to the clinical trial can be found on the Company's website at https://www.scancell.co.uk and at https://classic.clinicaltrials.gov/ct2/show/NCT04079166

About the ModiFY Phase 1/2 clinical trial

ModiFY is an open-label, multicohort, multicentre, adaptive Phase 1/2 trial of Modi-1 in patients with unresectable head and neck, ovarian, triple negative breast and renal cancer. The Modi-1 peptides are linked to AMPLIVANT®, a potent adjuvant which is the subject of a worldwide licensing and collaboration agreement with ISA Pharmaceuticals for the manufacturing, development, and commercialisation of Modi-1. Modi-1 stimulates CD4 T cells which may directly impact tumour growth; however, in some patients these T cells may need to be protected by checkpoint inhibitors if the tumour environment is highly immunosuppressive. Patients are therefore treated with Modi-1 alone or, if eligible for standard of care CPI, with Modi-1 plus a CPI.

Cohort 1 of the study confirmed the safety profile of a low dose of two citrullinated vimentin peptides. The objective for Cohort 2 of the trial was to assess the safety of the two citrullinated vimentin peptides plus an enolase peptide at a higher dose. Based on the safety data from Cohort 2, the ModiFY trial was expanded at this recommended Phase 2 dose for Modi-1 monotherapy in all four tumour types. In parallel, Cohort 3 recruited patients to receive low dose Modi-1 plus a CPI to assess safety of the combination prior to testing the higher dose of Modi-1 in Cohort 4.

Further information relating to the clinical trial can be found on the Company's website at https://www.scancell.co.uk and at https://clinicaltrials.gov/ct2/show/NCT05329532

About Scancell

Scancell is a clinical stage biopharmaceutical company that is leveraging its proprietary research, built up over many years of studying the human adaptive immune system, to generate novel medicines to treat significant unmet needs in cancer and infectious disease. The Company is building a pipeline of innovative products by utilising its four technology platforms: Moditope® and ImmunoBody® for vaccines and GlyMab® and AvidiMab® for antibodies.

Adaptive immune responses include antibodies and T cells (CD4 and CD8), both of which can recognise damaged or infected cells. In order to destroy such cancerous or infected cells, Scancell uses either vaccines to induce immune responses or monoclonal antibodies (mAbs) to redirect immune cells or drugs. The Company’s unique approach is that its innovative products target modifications of proteins and lipids. For the vaccines (Moditope® and ImmunoBody®) this includes citrullination and homocitrullination of proteins, whereas its mAb portfolio targets glycans or sugars that are added onto proteins and / or lipids (GlyMab®) or enhances the potency of antibodies and their ability to directly kill tumour cells (AvidiMab®).

For further information about Scancell, please visit: https://www.scancell.co.uk/