10 July 2023

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

Pipeline strategy and business update

- *Strategy to focus on development of Company's two lead clinical assets SCIB1 and Modi-1*
- *Phase 2 SCOPE trial testing SCIB1 or iSCIB1+ in combination with checkpoint inhibitors in metastatic melanoma patients is progressing well with potential pathway for a registration trial*
- *44% disease control rate (DCR) in ovarian cancer patients in ModiFY monotherapy trial*
- *Cash runway to 2H 2024 which covers near-term inflection points and cohort expansions*

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, provides an update on its two ongoing Phase 1/2 clinical trials with lead cancer vaccine assets SCIB1/iSCIB-1+ and Modi-1. Encouraging data from these open label studies provides validation for the Company's decision to concentrate its strategic focus and resources on these two assets.

"I am very encouraged by the data we have seen so far from both the SCOPE trial with SCIB1 and the ModiFY trial with Modi-1, which support the decision to sharpen our focus on these two assets" **said Scancell CEO Lindy Durrant**. "With SCIB1 we have a clear potential development pathway involving a registration trial which could move this product rapidly towards the market. Additionally, I am pleased to see that Modi-1 is having an effect on disease control in ovarian cancer in these very heavily pre-treated patients, although we believe the true value of our vaccine is probably in combination with checkpoint inhibitors. We remain well positioned and funded to continue the development of these high-potential assets to the next near-term value inflection points."

SCIB1/iSCIB1+

The open-label, Phase 2 single arm SCOPE trial is investigating the safety and tolerability of using SCIB1/iSCIB1+, Scancell's lead ImmunoBody® cancer vaccine, in combination with checkpoint inhibitors in patients with advanced melanoma. The current trial is designed to determine whether any clinical effect is unlikely to be due to checkpoints alone based on the rate of clinical responses in each cohort, i.e., with either a single or double checkpoint combination.

The trial is progressing well, with 73% of the required number of patients receiving SCIB1 in combination with two checkpoint inhibitors (ipilimumab and nivolumab) recruited to date. Scancell expects the initial topline data readout from this double checkpoint arm of the study in Q4 2023.

Following the data readout, Scancell intends to initiate a similar double checkpoint cohort with iSCIB1+ before the end of the year. iSCIB1+ has a number of competitive advantages, with potentially increased potency due to modifications to the product using Scancell's propriety AvidiMab® platform, and an extended patent life to 2039. iSCIB1+ is able to be used by a broader patient population because it incorporates more melanoma-specific epitopes.

If positive, data generated by iSCIB1+ could lead to the initiation of a potential, rapid clinical development programme in H2 2024. An adapted registration trial could yield Phase 2 data within 2 years and would provide the Company with a pathway to a potential deal. The Phase 3 data could be complete within the following 3 years.

Modi-1

Modi-1 is the first vaccine based on Scancell's Moditope® platform. Recruitment is progressing well in the ModiFY open-label Phase 2a dose expansion study investigating the safety, tolerability and preliminary efficacy of Modi-1 as a monotherapy and in combination with checkpoint inhibitors in patients with ovarian, triple negative breast, renal and head and neck cancers.

The cohort of 16 ovarian cancer patients receiving Modi-1 has now been fully recruited. All patients had failed on previous treatments and their disease was actively progressing when they entered the study. Following treatment with Modi-1 44% of patients achieved stable disease for at least 8 weeks, with some patients experiencing a longer duration of disease stability for 4 months or more. Four patients are still ongoing in this cohort.

Dr David Pinato, Principal Investigator at Imperial College, commented: *"Advanced ovarian cancer is an aggressive cancer which is hard to treat. A disease control rate of 44% with Modi-1 in patients who have exhausted most treatment options is very encouraging".*

The number of patients who have experienced long periods of stable disease following monotherapy with Modi-1 is encouraging in this difficult to treat cancer and the Company believes that combination therapy with checkpoint inhibitors, which are not currently approved for the treatment of ovarian cancer, could further improve outcomes for this patient group. Evaluation of Modi-1 plus checkpoint inhibitors in other tumour types in the ongoing Phase 1/2 study, will provide supporting data for this proposed combination use.

In the other monotherapy cancer cohorts, a total of eight patients have received full dose Modi-1

- One TNBC patient remains on trial with stable disease beyond 8 weeks
- One head and neck patient achieved a partial response and remains on study at week 37

Additionally, Scancell has recruited a fourth cohort of three patients receiving full dose Modi-1 in combination with the checkpoint inhibitor nivolumab. Subject to a safety committee review meeting scheduled to take place in August, this cohort will be expanded to 21 patients in both head and neck and renal cancer. Preliminary topline data from these cohorts is expected to be reported in 2024.

Antibody platform

Scancell has developed a novel technology platform for producing monoclonal antibodies that recognise glycans with high specificity and affinity. The platform has generated revenues and the antibodies continue to yield compelling results which have led to a new 6-month evaluation by a leading Biotech company. Additional in-house data has illustrated the potential of our antibodies as chimeric antigen receptor T cell (CART) therapies providing the data for a deal with a cell therapy company. These results along with updates on SCIB1 and Modi-1 will be presented at the AACR-CIMT meeting in Milan in September 2023.

Due to the company increasing focus on its two clinical assets, Scancell is fully funded to 2H 2024 including the near-term data inflection points and near-term cohort expansions outlined above.

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.

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/