22 June 2021

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

COVIDITY Phase 1 clinical trial planned in South Africa and UK for novel bivalent COVID-19 vaccine

COVIDITY programme based on modification of Company's ImmunoBody® platform; Published preclinical data supports transition to the clinic

Versatile and efficient approach can potentially protect against variants of concern

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, today announces an update on COVIDITY clinical trial plans and the publication of preclinical data on two vaccine candidates from its COVIDITY research programme. The COVIDITY programme is a collaboration between Scancell and scientists in the newly established Centre for Research on Global Virus Infections and the new Biodiscovery Institute at the University of Nottingham, and Nottingham Trent University and the programme has received funding from Innovate UK. Following findings from the preclinical data, a Phase 1 study on this next generation vaccine will commence in both South Africa and the UK in the second half of this year subject to local regulatory approvals.

Preclinical data published on vaccine candidates SCOV1 (SN15) and SCOV2 (SN17)

The Company is pleased to note the publication of preclinical data on its two lead bivalent vaccine candidates SN15 (also known as SCOV1) and SN17 (also known as SCOV2). These next generation COVID-19 vaccines could offer improved protection against new SARS-Cov-2 variants of concern (VoC) due to the inclusion of the highly conserved nucleocapsid N antigen in addition to the more variable spike (S) protein. Based on the potent immune responses generated in these preclinical studies, Scancell plans to test the safety and immunogenicity of SCOV1 and SCOV2 in a Phase 1 clinical trial.

SCOV1 and SCOV2 are based on a modification of Scancell's ImmunoBody® DNA vaccine technology and have a dual mechanism of action to induce high avidity T-cell immune responses against both the N and S viral antigens. Targeting the receptor-binding domain (RBD) of the S antigen, the vaccines also elicit high titre virus-neutralising antibodies (VNAbs) that can cross-react against a range of VoCs, including the Beta variant first identified in South Africa.

The paper shows that SN15 elicits strong pro-inflammatory T-cell responses to both the N and S proteins, with these responses being significantly enhanced by fusing the nucleocapsid sequence to a modified Fc utilising Scancell's AvidiMab™ technology. The SN15 vaccine also stimulates high titre neutralising antibody (VNAbs) responses to the receptor binding domain (RBD) of the S protein and shows cross reactivity with S proteins from the emerging variants Alpha (B.1.1.7; Kent) and Beta (B.1.351; South African).

The Company believes this DNA platform can be easily adapted to target variant RBD and N proteins and demonstrates that SN17, encoding the Beta RBD sequence, stimulates cross-reactive antibody mediated and T-cell immunity. The paper supports the translation of this DNA vaccine platform into the clinic, thereby offering a particular advantage for targeting emerging SARS-CoV-2 variants.

Prof Lindy Durrant, Founder and Chief Scientific Officer, Scancell, **commented**: *"We believe that the combination of cross-reactive VNAbs with durable memory responses against the conserved N protein may confer an added advantage by eliciting potent T cells that can destroy cells infected with any of the variant viruses, providing an extra layer of protective surveillance."*

The preclinical data and paper titled "A novel bivalent DNA vaccine encoding both spike protein receptor-binding domain and nucleocapsid protein of SARS-CoV-2 to elicit T cell and neutralising antibody responses that cross react with variants" can be viewed via BioRxiv with the following link: https://www.biorxiv.org/content/10.1101/2021.06.18.448932v1.

Part 1 of clinical trial (South Africa)

A regulatory application to initiate a Phase 1 clinical trial of COVIDITY has been submitted to the South African Health Products Regulatory Authority (SAHPRA). Part 1 of this study will be conducted at the University of

Cape Town Lung Institute, South Africa, in COVID-19-naïve unvaccinated, healthy adult volunteers. Such a study is not possible in the UK because of the rapid rollout of the vaccination programme.

The objective of the study will be to assess the safety and immunogenicity of the two candidates in unvaccinated individuals and will have two cohorts assessing different doses of SCOV1 and SCOV2 using two different needle-free injection methods. In addition to evaluating the VNAbs, the Company will also analyse the T cell responses to the N protein, which will provide additional information and data on the potential utility of both SCOV1 and SCOV2 against future SARS-CoV-2 variants.

Part 2 of clinical trial (UK)

After demonstration of safety in Part 1 of the COVIDITY study in South Africa, Scancell will seek approval from the Medicines & Healthcare products Regulatory Agency (MHRA) to initiate a UK extension of the study in which SCOV2 will be given to healthy volunteers who have already received two doses of an approved vaccine. The immune responses from this UK part of the COVIDITY study will allow the Company to assess the ability of SCOV2 to boost the immune response against current and potential future strains of COVID-19 in pre-vaccinated individuals.

Vaccine manufacturing

As reported in October 2020, the Company entered into a collaboration with Cobra Biologics, part of the Cognate BioServices family, to conduct preliminary work leading to the manufacture of plasmids for Scancell's COVID-19 vaccine. The collaboration is progressing to plan to ensure that Good Manufacturing Practice (GMP) grade SCOV1 clinical trial supplies are available for initiation of the COVIDITY study followed by SCOV2 supplies for further clinical assessments.

Dr Cliff Holloway, Chief Executive Officer, Scancell, commented: *"There is a significant threat from future mutations of the SARS-CoV-2 virus, as we have seen with the rapid transmission of the Delta variant. Our next generation COVID-19 vaccine has the potential to work alongside currently approved vaccines by protecting the population against new variants of SARS-CoV-2. We look forward to initiating this trial in South Africa and the UK, and to updating the market in due course on further developments from the COVIDITY programme."*

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

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About Scancell

Scancell is developing novel immunotherapies for the treatment of cancer based on its technology platforms, ImmunoBody®, Moditope® and AvidiMab™, with four products in multiple cancer indications and development of a vaccine for COVID-19.

ImmunoBody® vaccines target dendritic cells and stimulate both CD4 and CD8 T cells with the ability to identify, target and eliminate cancer cells. These cancer vaccines have the potential to be used as monotherapy or in combination with checkpoint inhibitors and other agents. The Directors believe that this platform has the potential to enhance tumour destruction, prevent disease recurrence and extend survival.

- SCIB1, Scancell's lead product, is being developed for the treatment of metastatic melanoma. In a Phase 1/2 clinical trial, survival with SCIB1 treatment appears superior to historical survival rates, with 14 of 16 resected patients receiving 2-4 mg doses of SCIB1 surviving for more than five years.

- SCIB2 is being developed for the treatment of non-small cell lung cancer and other solid tumours.

DNA vaccine against COVID-19: As research data emerges, it is becoming increasingly clear that the induction of potent and activated T cells may play a critical role in the development of long-term immunity and clearance of virus-infected cells. Initial research is underway and Scancell anticipates initiating a Phase 1 clinical trial known as COVIDITY during 2021.

Moditope® represents a completely new class of potent and selective immunotherapy agents based on stress-induced post-translational modifications (siPTM). Examples of such modifications are citrullination, an enzyme-based conversion of arginine to citrulline, and homocitrullination (or carbamylation), in which lysine residues are converted to homocitrulline. Expression of peptides containing these modifications have been demonstrated to induce potent CD4 cytotoxic t cells to eliminate cancer. Previous pre-clinical studies have demonstrated that conjugation of these Moditope® peptides to Amplivant® enhances anti-tumour immune responses 10-100 fold and resulted in highly efficient tumour eradication, including protection against tumour recurrence.

- Modi-1 consists of two citrullinated vimentin peptides and one citrullinated enolase peptide each conjugated to Amplivant®. Vimentin and enolase peptides are highly expressed in triple negative breast, ovarian, head and neck, and renal cancer, as well as many other cancers. The Company continues to progress the Modi-1 Phase 1/2 clinical trial for regulatory submission in the first half of 2021.

AvidiMab™ has broad potential to increase the avidity or potency of any therapeutic monoclonal antibody (mAb) including those being developed for autoimmune diseases, as well as cancer. Scancell's development pipeline includes mAbs against specific tumour-associated glycans (TaGs) with superior affinity and selectivity profiles, that have now been further engineered using the Company's AvidiMab™ technology; this confers the Scancell anti-TaG mAbs with the ability to directly kill tumour cells. The Company has entered into three non-exclusive research agreements with leading antibody technology companies to evaluate the Company's anti-TaG mAbs including those enhanced with the AvidiMab™ technology.