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

COVIDITY Phase 1 clinical trial application in South Africa approved

COVIDITY clinical trial expected to initiate in H2 2021

Scancell's COVID-19 vaccine candidates aim to protect against all COVID-19 Variants of Concern

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, today announces that the South African Health Products Regulatory Authority (SAHPRA) has approved the clinical trial application (CTA) for the Phase 1 clinical study of COVIDITY (COVIDITY-001) in South Africa.

The COVIDITY programme, focused on the Company's novel COVID-19 vaccine candidates SCOV1 and SCOV2, 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. The programme has received funding from Innovate UK.

SCOV1 and SCOV2, targeting the original and variant SARS-CoV-2 viruses, respectively, 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 cross-react against a range of Variants of Concern (VoC), including the new Delta variant.

Professor Lindy Durrant, Chief Executive Officer, Scancell, **commented:** *"We are very pleased that this CTA was approved so rapidly, reflecting the importance of the study in South Africa, and it is a testament to the dedication and professionalism of the Scancell team and our colleagues in Cape Town. Our approach of targeting the conserved N protein in addition to generating potent, cross-reactive VNAbs has the potential to provide a significant clinical advantage by eliciting potent T cells that can destroy cells infected with any SARS-CoV-2 variants and other SARS-CoV viruses that may emerge in the future."*

COVIDITY-001 Part 1 (South Africa)

The regulatory application to initiate a Phase 1 clinical trial of COVIDITY has been approved by the South African Health Products Regulatory Authority (SAHPRA) and it is anticipated that the study will start in H2 2021. This part of the study will be conducted at the University of Cape Town Lung Institute, South Africa, in unvaccinated, healthy adult volunteers. UK sites could not be included in this part of the study due to the rapid rollout of the UK vaccination programme and resulting lack of vaccine-naïve subjects required for the initial safety evaluation.

The objectives will be to assess the safety and immunogenicity of the two vaccine candidates, SCOV1 and SCOV2, evaluating different vaccine doses delivered by two alterative injection routes using needle-free systems. 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.

COVIDITY-001 Part 2 (UK & South Africa)

After demonstration of safety in Part 1 of the 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 COVIDITY will be given to healthy volunteers who have already received two doses of an approved vaccine. The immune responses from this 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.

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.

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.