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

Modi-1 Phase I/II clinical trial application approved by MHRA

First-in-human clinical trial in patients with triple negative breast cancer, ovarian cancer, head and neck cancer, and renal cancer

Modi-1 to be administered in combination with checkpoint inhibitors in patients with head and neck or renal tumours

Patient enrolment expected to begin in H2 21

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, today announces that the UK's Medicines and Healthcare Products Regulatory Authority (MHRA) has approved the clinical trial application (CTA) to initiate the first-in-human Phase I/II clinical study of Modi-1. The Company expects to enrol patients into the study in H2 21, following ethics committee sign-off. Initial safety/tolerability data from the initial open label portion of the trial could be available from H1 22.

The Modi-1 clinical trial will be a first-in-human clinical trial in patients with triple negative breast cancer, ovarian cancer, head and neck cancer, and renal cancer. Modi-1 will be administered in combination with checkpoint inhibitors in patients with head and neck or renal tumours. The trial will initially focus on the safety of two citrullinated vimentin peptides and, if there are no significant side effects, a citrullinated enolase peptide will be added.

The Modi-1 peptides are linked to AMPLIVANT[®], a potent adjuvant which enhanced the immune response 10-100 fold and resulted in highly efficient tumour clearance, including protection against tumour recurrence, in preclinical models. AMPLIVANT[®] is the subject of a worldwide licensing and collaboration agreement with ISA Pharmaceuticals for the manufacturing, development and commercialisation of Modi-1.

The Modi-1 clinical trial will evaluate the first therapeutic vaccine candidate from the Company's novel Moditope[®] platform, which stimulates immune responses to stress induced post-translational modifications (siPTMs). When cells become stressed, they modify their proteins to alert the immune response that there is a problem. One of these modifications is citrullination which is the target for the Modi-1 vaccine. Fast growing cancer cells need a lot of oxygen and nutrients and are always highly stressed. Included in the Modi-1 vaccine are specific T cell epitopes derived from citrullinated vimentin, which is involved in tumour spread, and citrullinated enolase, which is an enzyme that generates nutrients to drive tumour growth. Removal of cells expressing these proteins by vaccine-specific T cells should eradicate the tumour and prevent further spread.

Professor Lindy Durrant, Chief Executive Officer, Scancell, commented: *"The approval of the Modi-1 CTA is a significant achievement for the Company. Targeting siPTMs generated dramatic regression of large tumours in our preclinical models and we hope to see similar results in cancer patients during this trial. This is the first of several vaccines that we are developing from the Moditope[®] platform and look forward to updating the market on our progress in due course."*

Professor Christian Ottensmeier at The Clatterbridge Cancer Centre and University of Liverpool, commented: *"I am very excited to be the principal investigator for this first-in-human clinical trial to determine if siPTMs and, in particular, citrullination will be able to transform the prognosis for these patients with hard to treat tumours."*

Professor Kees Melief, Chief Scientific Officer, ISA Pharmaceuticals, commented: *"We are delighted to be collaborating with Scancell on this innovative trial. We have shown that AMPLIVANT[®] is an excellent adjuvant for therapeutic vaccines and think that extending the scope of our technology to targeting siPTMs could have enormous benefit for patients with a range of solid tumours."*

Julie Crane, Centre Manager of Liverpool Head and Neck Centre (LHNC), commented: *"On behalf of LHNC, I am delighted that this exciting novel, first-in-human treatment will be available for our head and neck patients."*

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.

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 (siPTMs). 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. The Directors believe that this platform has the potential to eradicate hard to treat solid tumours.

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 mAbs targeting TaGs can also be used to deliver cytotoxic payload to cancer or to redirect T 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.