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

Modi-1 trial open for expansion in combination with checkpoint inhibitors

- *Safety review committee has approved cohort expansion into renal and head and neck patients who receive CPI as standard of care alone and in the neoadjuvant setting*
 - *Cohort 4 of the ModiFY trial showed that the higher dose Modi-1 in combination with CPI was well tolerated with no safety concerns*

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, announces that the ModiFY trial is now open for expansion in combination with checkpoint inhibitors (CPI) and in the neoadjuvant setting.

Following the successful completion of Cohort 4, where three patients received at least two doses of Modi-1 combined with CPI, the safety review committee has approved expansion into two cohorts of patients with renal or head and neck cancer who receive CPI as standard of care. 21 patients will be recruited into each cohort. Patients with triple negative breast cancer will not be included in this part of the study as these patients receive checkpoints in combination with chemotherapy which may induce citrullination in normal cells and induce toxicity.

Additionally, recruitment into the neoadjuvant arm of the Modi-1 trial in combination with CPI was also approved. This study will recruit 30 patients who will be randomised at diagnosis to receive either two doses of Modi-1 three weeks apart or two doses of Modi-1 plus one dose of CPI. Tumour biopsies will be taken prior to immunisation and from the tumour resection 6 weeks following the initial vaccination. The two tumour samples will allow the extent of T cell infiltration and activation pre- and post-Modi-1 vaccination to be assessed with and without a checkpoint inhibitor.

Modi-1 treatment were well tolerated in Cohort 4 with no safety concerns. Encouragingly, the first patient to be assessed has shown a tumour regression at their first radiological assessment at 8 weeks. The remaining patients have not yet been assessed radiologically.

Prof Lindy Durrant, Chief Executive Officer, Scancell, commented: *"This is an important milestone for the Company as we now have approval to treat patients with Modi-1 monotherapy or in combination with a CPI in four different tumour types either pre- or post-tumour resection. The information extracted from this study will be invaluable in defining the patient population that will benefit the most from our cancer vaccine, Modi-1."*

The Company expects further safety, immunogenicity and efficacy data to be available in 2023.

For further information, please contact:

Scancell Holdings plc +44 (0) 20 3709 5700

Professor Lindy Durrant, CEO
Dr Jean-Michel Cosséry, Non-Executive Chairman

Stifel Nicolaus Europe Limited (Nominated Adviser and Joint Broker) +44 (0) 20 7710 7600
Nicholas Moore/Samira Essebiyea/William Palmer-Brown (Healthcare Investment Banking)
Nick Adams/Nick Harland (Corporate Broking)

Panmure Gordon (UK) Limited (Joint Broker) +44 (0) 20 7886 2500
Freddy Crossley/Emma Earl (Corporate Finance)
Rupert Dearden (Corporate Broking)

Consilium Strategic Communications +44 (0) 20 3709 5700

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/>

About the ModiFY trial

Modi-1 is the first candidate in Scancell's Moditope[®] platform. The ModiFY study is a multicentre Phase 1 open label first-in-human clinical trial with Modi-1, an innovative cancer vaccine targeting citrullination in cancer, being administered alone or in combination with CPIs in patients with head and neck, triple negative breast and renal tumours and as a monotherapy in patients with ovarian cancer, where there are no approved CPI therapies and in patients with the other tumour types where CPIs are not indicated. Modi-1 stimulates CD4 T cells which may directly impact tumour growth however in some patients if the tumour environment is highly immunosuppressive, these T cells may need to be protected by CPIs. This open label Phase 1 study is assessing the safety and immunogenicity of two citrullinated vimentin peptides and a citrullinated enolase peptide.