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

Scancell receives MHRA approval to expand ModiFY trial

Modi-1 to be assessed in renal cell carcinoma in combination with double checkpoint inhibitors

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer, today announces that, following further discussions with the Medicines and Healthcare products Regulatory Agency (MHRA), it has received approval to add an expansion cohort to the ModiFY trial. This cohort will recruit 44 previously untreated renal cell carcinoma (RCC) patients who will receive Scancell's Modi-1 cancer vaccine in combination with doublet checkpoint inhibitor (CPI) therapy, consisting of ipilimumab (Yervoy®) plus nivolumab (Opdivo®).

Early data from patients receiving Modi-1 as a monotherapy have demonstrated stable disease, good T cell responses, safety and tolerability, with the absence of dose limiting toxicities in dose escalation cohorts. Modi-1 is also being used to treat head and neck cancer patients who receive single CPI as standard of care. Treatment of patients with advanced or metastatic RCC in the first-line setting consists of double CPI therapy. The addition of Modi-1 to this cohort will enable the testing of the synergistic effect of Modi-1 peptides in improving the overall response rate, as demonstrated in our SCOPE trial, showing that the double checkpoints are ideal in synergising with targeted vaccines.

Dr Stefan N Symeonides, Consultant Medical Oncologist & Senior Lecturer in Experimental Cancer Medicine, University of Edinburgh, said "The addition of Modi-1 to ipilimumab with nivolumab in patients with untreated renal cell carcinoma in the ModiFY basket study will address important clinical and immunological questions. The outcomes from this cohort will help with patient selection for the subsequent phases of clinical development of Modi-1."

Prof Lindy Durrant, Chief Executive Officer, Scancell said: "We greatly appreciate the supportive and helpful discussions with the MHRA and are thrilled to have received approval to expand ModiFY into a cohort of patients who will now receive Modi-1 in combination with double checkpoint inhibitors. This approval marks another milestone for Scancell, and the promising efficacy, safety and tolerability study generated from earlier cohorts underscore our belief that our Modi-1 cancer vaccine has the potential to deliver a step change in the treatment of renal and other hard-to-treat cancers."

The Company expects early clinical data from patients treated with Modi-1 plus CPIs later this year.

-ENDS-

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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. 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 1/2 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 and renal tumours and as a monotherapy in patients with ovarian cancer, triple negative breast and renal cancer. 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 1/2 study is assessing the safety and immunogenicity of two citrullinated vimentin peptides and a citrullinated enolase peptide.