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

Scancell's Modi-1 Moditope® Vaccine Achieves Early Clinical Validation in Head and Neck Cancer

Modi-1 successfully achieved Simon stage 1 suggesting the combination of Modi-1 and checkpoint blockade is beneficial in HPV negative head and neck squamous cell carcinoma (SCCHN)

This result supports the continuation of the study in this indication

Moditope® patent granted by U.S. Patent and Trademark Office (USPTO)

Scancell Holdings plc (AIM: SCLP), a clinical-stage biopharmaceutical company developing novel immunotherapies for cancer, has achieved significant clinical and commercial milestones in its *ModiFY* study.

Modi-1, the lead vaccine from Scancell's Moditope® platform, is being investigated in the open-label Phase 2a dose expansion *ModiFY* study. This trial evaluates the safety, tolerability, and preliminary efficacy of Modi-1 in combination with checkpoint inhibitors (CPIs) in patients with renal and head and neck cancers.

The cohort investigating HPV negative head and neck squamous cell carcinoma (SCCHN) was designed to determine if the overall objective response rate (ORR) in patients could be improved by combining Modi-1 Moditope® in combination with standard of care single agent checkpoint inhibitor pembrolizumab. Three of the seven evaluable patients that have received immunisation with Modi-1 Moditope® combined with a checkpoint inhibitor have demonstrated a partial response as determined by RECIST 1.1 tumour assessment at their 25-week scan. This equates to an ORR of 43% compared to historical ORRs of 19% for Pembrolizumab and 13% for nivolumab. In view of the significant improvement in response rate and the good safety and tolerability, this study is well positioned to continue enrolment into Simon stage 2. These encouraging early results will be further verified upon completion of this HPV (-) SCCHN Modi-1 Moditope ® + CPI cohort, after a total of up to 21 patients have been vaccinated. In addition, there is investigator interest to evaluate Modi-1Moditope® in the neoadjuvant setting for this indication.

The commercial positioning of Modi-1 Moditope® has been further strengthened through approval by the U.S. Patent and Trademark Office (USPTO) for a patent for Moditope® and successful formulation development. The patent from the USPTO will add to the protection of the Company's pipeline of Moditope® vaccines for the treatment of cancer, which has already been granted by the European Patent Office, along with China, Japan and Australia.

Dr Nermeen Varawalla, Chief Medical Officer Scancell commented: *"The promising early Simon stage 1 (non-futility) read-out from the (HPV negative) SCCHN cohort of the ModiFY Phase 2 clinical study sets the stage for Simon stage 2 and the further development of Modi-1 Moditope® in a cancer indication with poor outcomes following standard of care."*

Chief Investigator Christian Ottensmeier, Professor of Immuno-Oncology at Head and Neck Institute, University of Liverpool, commented: *"This positive preliminary clinical read-out validates the scientific rationale for Moditope® vaccines as a therapy with real potential to improve outcomes achievable with checkpoint inhibitors alone. Given its good safety profile and ease of use, I remain keen to continue using this vaccine as well as explore the application of Modi-1 in the neoadjuvant setting."*

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

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About Moditope®

Moditope® is a unique class of potent off the shelf peptide vaccine targeting tumour-specific neoantigens generated from

stress-induced post translational modifications (siPTMs) activating CD4 cytotoxic T cells via the MHC-II presentation pathway. Modi-1 Moditope® is the lead vaccine from the Scancell Moditope® platform. Modi-1 Moditope® targets citrullinated peptides, combining peptides from two different proteins combined to reduce the possibility of tumour escape. Potent T cell responses and strong anti-tumour activity have been observed in several cancer models of different tumour types, including squamous cell carcinoma of the head and neck, ovarian, renal cell cancer and triple negative breast cancer, following administration of the Modi-1 vaccine.

About the ModiFY trial

Modi-1 Moditope® is the lead candidate from the Scancell Moditope® platform. The ModiFY study is a multicentre Phase 1/2 open label first-in-human clinical trial with Modi-1 Moditope®, 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, squamous cell carcinoma of the head and neck 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 currently assessing the safety and immunogenicity of the Modi-1 Moditope® subtype, Modi-1ev, comprising two citrullinated vimentin peptides and a citrullinated enolase peptide.

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/

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