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This announcement contains inside information for the purposes of Article 7 of the UK version of Regulation (EU) No 596/2014 which is part of UK law by virtue of the European Union (Withdrawal) Act 2018, as amended ("MAR"). Upon the publication of this announcement via a Regulatory Information Service, this inside information is now considered to be in the public domain.

Scancell Holdings plc
(“Scancell” or the “Company”)

Update on SCOPE trial

MHRA approval to add a third cohort using iSCIB1+ to the SCOPE trial

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, announces today that following further discussions with the Medicines and Healthcare products Regulatory Agency (MHRA), it has now received approval to add a third cohort to the SCOPE trial. This cohort will recruit 43 advanced unresectable melanoma patients who will receive iSCIB1+ with doublet therapy, consisting of ipilimumab (Yervoy®) plus nivolumab (Opdivo®).

iSCIB1+ is a modified version of SCIB1 developed using Scancell’s AvidiMab® platform to enhance its potency compared to SCIB1 and gives 15 years of extended patent protection. iSCIB1+ also includes additional melanoma-specific epitopes so it has the potential to be effective in a broader patient population beyond the 40% of patients with the tissue type treatable with SCIB1, where treatment is HLA dependent.

Exceptional results from the first 13 patients receiving SCIB1 in the ongoing SCOPE trial, with an objective response rate of 85%, indicate a high probability of success in this cohort which should complete in Q2 2024. Recruitment into the iSCIB1+ cohort is expected to be complete by the end of Q2 2024, with early data expected in Q3 2024.

The results from these SCIB1 and iSCIB1+ cohorts, administered in combination with doublet therapy, will enable the Company to make a data-led decision regarding initiation of a randomised Phase 2/3 adapted registration programme in patients with unresectable melanoma, which represents a potential \$1.5 billion per annum market. The Phase 2 part of the adapted trial is anticipated to take 18 months, with the potential to generate attractive licensing opportunities.

Prof Lindy Durrant, Chief Executive Officer, Scancell, commented: *“Thanks to the excellent work done by the Scancell team, working hand in hand with a responsive MHRA, we are pleased to report today that we have received approval to include a third cohort of patients in the SCOPE trial who will now receive iSCIB1+ in combination with doublet checkpoints. We anticipate that iSCIB1+ will be as effective as SCIB1 and, with its potentially increased potency and broader patient profile, make it a promising candidate for registration studies. We look forward to providing further updates on our progress given the extremely positive results to date.”*

-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 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/>

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