

18 April 2023

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

Scancell to present ModiFY Phase 1/2 cancer vaccine clinical trial protocol and early efficacy data at the American Association for Cancer Research Annual Meeting

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, announces it will today present a poster entitled “*Modi-1, anti-citrullinated neoepitope vaccine alone and combined with checkpoint inhibitors in patients with head and neck, breast, renal and ovarian carcinoma: protocol for the ModiFY phase I/II basket clinical trial*” at the American Association for Cancer Research (AACR) 2023 Annual Meeting taking place at the Orange County Convention Center in Orlando, Florida, US between 14-19 April 2023.

The poster being presented by Fayaz Master, Head of Clinical Operations, describes the protocol and introduces the concept of citrullination as a good target for cancer vaccines. This is exemplified by presenting the results reported by the Company on 21 February on the ModiFY trial. This is a first-in-human Phase 1/2 basket trial investigating the use of Modi-1, the first candidate from Scancell’s Moditope® platform, to treat four different types of cancer: high grade serous ovarian carcinoma (HGSOC), triple negative breast cancer (TNBC), head and neck squamous cell carcinoma (SCCHN) and renal cell carcinoma (RCC).

The poster, which includes data up until the date of the poster acceptance by AACR, concludes that Modi-1 is well tolerated and that the early efficacy data from the monotherapy arm of the trial is encouraging. Safety and early efficacy data are supportive of the current ongoing sub-studies with Modi-1 in combination with standard of care checkpoint inhibitor (CPI) therapy. Over 20 patients had been vaccinated with Modi-1 and all had skin reactions at the injection sites consistent with a delayed-type hypersensitivity (DTH) reaction indicative of a T cell response. Initial clinical responses had been assessed in 14 patients reaching the first imaging evaluation timepoint at week 8. Of these patients, one had a confirmed partial response and seven patients had had stable disease, despite having progressive disease prior to enrolment in the study.

The ModiFY study is ongoing and recruiting patients into the Phase 2a sub-study investigating Modi-1 monotherapy in dose expansion cohorts. In tandem, patients are being screened for treatment with Modi-1 in combination with standard of care CPI therapy. The safety, efficacy and immunology of Modi-1 will continue to be evaluated in up to 138 cancer patients within the master protocol.

The title, timing and location of the poster presentation are as follows:

Abstract [CT256/19](#)

Poster presentation title Modi-1, anti-citrullinated neoepitope vaccine alone and combined with checkpoint inhibitors in patients with head and neck, breast, renal and ovarian carcinoma: protocol for the ModiFY phase I/II basket clinical trial

Session title Phase I and First-in-Human Clinical Trials in Progress

Session date and time 13:30 – 17:30 ET, 18 April 2023

Location Orange County Convention Center, Section 46, Poster Board Number 19

Copies of the poster will be available on Scancell’s website following the conference at: <https://www.scancell.co.uk/vaccine-publications>

For further information, please contact:

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

+44 (0) 20 3727 1000

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)

FTI Consulting +44 (0) 20 3727 1000
Simon Conway/Rob Winder/Alex Davis

About the ModiFY Phase 1/2 clinical trial

ModiFY is an open-label, multicohort, multicentre, adaptive Phase 1/2 trial of Modi-1 in patients with unresectable HGSOE, SCCHN, TNBC or RCC. The Modi-1 peptides are linked to AMPLIVANT[®], a potent adjuvant which is the subject of a worldwide licensing and collaboration agreement with ISA Pharmaceuticals for the manufacturing, development, and commercialisation of Modi-1. Modi-1 stimulates CD4 T cells which may directly impact tumour growth; however, in some patients these T cells may need to be protected by CPIs if the tumour environment is highly immunosuppressive. Patients are therefore treated with Modi-1 alone or, if eligible for standard of care CPI, with Modi-1 plus a CPI.

Cohort 1 of the study confirmed the safety profile of a low dose of two citrullinated vimentin peptides. The objective for Cohort 2 of the trial was to assess the safety of the two citrullinated vimentin peptides plus an enolase peptide at a higher dose. Based on the safety data from Cohort 2, the ModiFY trial was expanded at this recommended Phase 2 dose for Modi-1 monotherapy in all four tumour types. In parallel, Cohort 3 is recruiting patients to receive Modi-1 plus a CPI.

Further information relating to the clinical trial can be found on the Company's website at <https://www.scancell.co.uk> and at <https://clinicaltrials.gov/ct2/show/NCT05329532>

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/>