

# Scancell Holdings plc

("Scancell" or the "Company")

#### Encouraging early efficacy data from monotherapy part of ModiFY Phase 1/2 clinical trial

Modi-1 cancer vaccine showed partial response and stable disease in patients with hard-to-treat head and neck, high grade serous ovarian or triple negative breast cancers

### First clinical candidate from Moditope® platform well tolerated with no dose limiting toxicities

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, today announces completion of the monotherapy dose finding arm of the multicentre Phase 1/2 ModiFY clinical trial. Data from patients receiving the Modi-1 cancer vaccine as a monotherapy showed that it was safe and well tolerated and demonstrated encouraging early efficacy in a head and neck cancer patient and in other hard-to-treat cancers such as high grade serous ovarian carcinoma (HGSOC) and triple negative breast cancer (TNBC).

ModiFY is a first-in-human Phase 1/2 basket trial investigating the use of Modi-1, the first candidate from Scancell's Moditope<sup>®</sup> platform, to treat four different types of cancer: HGSOC, TNBC, head and neck squamous cell carcinoma (SCCHN) and renal cell carcinoma (RCC). A total of up to 138 cancer patients will be recruited into either the monotherapy groups of the trial, or treated in combination with standard of care checkpoint inhibitor (CPI) therapy, or if surgical candidates with SCCHN, they will be randomised to receive either Modi-1 alone or Modi-1 with pembrolizumab (Keytruda<sup>®</sup>).

To date, 23 patients have been vaccinated with Modi-1 and all have had skin reactions at the injection sites consistent with a delayed-type hypersensitivity (DTH) reaction indicative of a T cell response. So far, initial clinical responses have been assessed in 14 patients reaching the first imaging evaluation timepoint at week 8. Of these patients, one has had a confirmed partial response and seven patients have stable disease, despite having progressive disease prior to enrolment in the study. As no dose limiting toxicities were observed in the monotherapy dose escalation cohorts, patients continue to be enrolled into both the ongoing monotherapy expansion cohorts and the CPI combination dose escalation cohorts during H1 2023.

**Dr David Pinato, Principal Investigator at Imperial College, commented:** "Advanced ovarian cancer is an aggressive cancer which is hard to treat. The early efficacy data showing that the Modi-1 vaccine is stabilising this advanced disease is very encouraging".

**Prof Christian Ottensmeier, Chief Investigator, University of Liverpool commented:** "The strong DTH responses in all patients and the early clinical results, particularly in the patient with advanced SCCHN, suggests that this therapeutic cancer vaccine could have significant potential. Further studies with Modi-1 monotherapy and in combination with CPIs should tell us in which settings it will have maximum benefit to patients."

**Prof Lindy Durrant, Chief Executive Officer, Scancell, commented**: "We are highly encouraged with the early efficacy data we have achieved in the ModiFY clinical trial, and safety profile to date with patients receiving Modi-1. These results allow us to proceed with the monotherapy expansion cohorts and into the cohorts in combination with checkpoint inhibitors as planned."

### 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 HGSOC, 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. To date, 23 patients have been vaccinated, 18 with HGSOC, two with TNBC, two with SCCHN and one with RCC, with 55 doses being administered in total.

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

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

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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<sup>®</sup> and ImmunoBody<sup>®</sup> for vaccines and GlyMab<sup>®</sup> and AvidiMab<sup>®</sup> 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<sup>®</sup> and ImmunoBody<sup>®</sup>) this includes citrullination and homocitrullination of proteins, whereas its mAb portfolio targets glycans or sugars that are added onto proteins and / or lipids (GlyMab<sup>®</sup>) or enhances the potency of antibodies and their ability to directly kill tumour cells (AvidiMab<sup>®</sup>).

For further information about Scancell, please visit: <u>https://www.scancell.co.uk/</u>