

Scancell Holdings plc

Scancell initiates new arm (Cohort 4) in SCOPE Phase 2 study to evaluate intradermal administration and an accelerated dosing regimen for iSCIB1+

Cohort 4 evaluates iSCIB1+ immunotherapy for the treatment of advanced melanoma

No significant adverse events observed in initial 8 patients dosed intradermally with SCIB1+

Additional data from Cohorts 1-3 expected in July 2025

Interim data from Cohort 4 expected around the year end

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapy products for the treatment of multiple cancers, announces today that dosing of patients has commenced in Cohort 4 of its Phase 2 clinical SCOPE study. This cohort will evaluate iSCIB1+ Immunobody® through intradermal administration and accelerated dosing in patients with advanced unresectable melanoma.

The initial 8 patients have now been safely dosed in the fourth cohort with iSCIB1+, including patients recruited through the NHS Cancer Vaccine Launch Pad. No significant adverse events have been observed with intradermal dosing. The trial remains on track, with data from Cohorts 1 through 3 expected in July 2025. With ongoing strong recruitment continuing in the iSCIB1+ Cohort 4, initial data in this cohort is expected around the end of 2025.

Dr Nermeen Varawalla, Chief Medical Officer of Scancell, said: "The SCOPE data reported so far are highly encouraging, with SCIB1 immunotherapy showing excellent efficacy and long-term survival benefits that signal a meaningful improvement over standard of care. Initiation of Cohort 4 is an important milestone for our iSCIB1+ programme to evaluate intradermal administration on our path to towards randomised studies."

SCOPE (NCT04079166) is a Phase 2, multi-centre open-label study, investigating SCIB1/iSCIB1+, with checkpoint inhibitors (CPIs) in late-stage melanoma and will enroll 140+ patients across four cohorts. Initial data from 25 patients in Cohort 1, receiving first-generation SCIB1 ImmunoBody® in combination with checkpoint inhibitors, ipilimumab and nivolumab, showed 84% disease control rate, 80% progression free survival (PFS), with a 20% complete response (CR) rate, and 72% ORR, demonstrating a significant improvement over standard of care treatment.

Cohort 3, receiving next generation iSCIB1+ in combination with ipilimumab and nivolumab, has now been completely enrolled. Cohort 4 will evaluate intradermal administration of Scancell's iSCIB1+



Immunobody®, a potent and targeted "off-the-shelf" active immunotherapy, with accelerated dosing of the priming immunizations in patients with advanced unresectable melanoma.

Phil L'Huillier, Chief Executive Officer of Scancell, said: "We are making strong clinical and strategic progress across our portfolio. The continued momentum in the SCOPE study highlights the clinical potential of SCIB1, and the next generation iSCIB1+, to address the unmet needs in melanoma. Modi-1 continues on track for further data readouts in the year. We are also progressing plans on our commitment to unlock the full potential of our innovative GlyMab® platform by establishing Glymab Therapeutics Ltd. We are looking to bring focus to our product development execution across the portfolio while positioning ourselves to deliver future value through creating strategic optionality in a time of market headwinds."

Management will host a webcast on 25th June at 11.00 BST to outline further the design of clinical development path for SCIB1 and iSCIB1+ and provide a corporate update. There will be an opportunity to ask questions following the presentation. Please click <u>here</u> to register for the webcast.

For more information please contact:

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SCIB1 is the lead product from the Company's ImmunoBody® platform, which uses the body's immune system to identify, attack and destroy tumours. **iSCIB1+** is a modified version of SCIB1 developed using Scancell's AvidiMab® platform to enhance its potency compared to SCIB1. iSCIB1+ also includes additional melanoma-specific epitopes so it has the potential to be effective in a broad patient population.

The SCOPE study (NCT04079166) is a Phase 2, Multicentre, Open-Label, Study in Advanced Unresectable Melanoma. Patients receiving either Nivolumab plus Ipilimumab or Pembrolizumab as standard of care (SoC) will also be treated with SCIB1 or iSCB1+. The study aims to determine the efficacy and safety of SCIB1 or iSCIB1+ when added to these SoC therapies. Additional endpoints include disease control rate (DCR), duration of response (DOR), progression free survival (PFS), overall survival (OS). Participants receive up to 10 doses of either SCIB1 or iSCIB1+ using the PharmaJet Stratis® or Tropis needle-free injection devices. More information at clinicaltrials.gov.



Scancell (LSE:SCLP; www.scancell.co.uk) is a clinical stage biotechnology company developing targeted off-the-shelf immunotherapies which enhance long-lasting tumour specific immunity for a cancer-free future. Scancell's lead product, iSCIB1+ immunotherapy, has shown strong promise, showing clinically meaningful additional benefit when combined with checkpoint therapies. The second immunotherapy, Modi-1, is being investigated in a phase 2 study in a broad range of solid tumours. Scancell also has an exciting early-stage pipeline of high affinity GlyMab® antibodies targeting tumour specific glycans. Two GlyMab® antibodies are being developed by Genmab under license from Scancell.