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Scancell Holdings Plc
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Scancell announces FDA clearance of IND application for global Phase 3 trial of iSCIB1+ in advanced melanoma

Unlocks path towards registrational Phase 3 trial planned to start in 2026

Data from Phase 2 SCOPE trial show iSCIB1+ has potential to redefine standard of care (SoC)

iSCIB1+ shows an interim 24%-point improvement in progression free survival (PFS) over real world SoC and historic controls

Scancell Holdings plc (AIM: SCLP), the developer of active immunotherapies to treat cancer, announces the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for a registrational Phase 3 trial of its iSCIB1+ Immunobody® in advanced melanoma, with progression free survival as the agreed surrogate endpoint.

Scancell has completed the 140-patient SCOPE Phase 2, open-label, multi-centre study evaluating ImmunoBody® immunotherapies (SCIB1 and iSCIB1+) in combination with nivolumab plus ipilimumab in previously untreated unresectable stage IIIB/IV melanoma. In addition to demonstrating potentially best-in-class efficacy and durability, from the data analysis we have identified a selection marker to enrich the phase 3 trial for responders.

Dr Phil L'Huillier, CEO of Scancell, said: "This IND clearance creates a clear pathway for late-stage registrational development of our iSCIB1+ Immunobody®. Data from the Phase 2 SCOPE trial shows a significant improvement in progression free survival as well as emerging overall survival with iSCIB1+ compared to historic benchmarks. I take this endorsement of our program as a strong measure of the clinical benefit and safety of our very novel product as well as the quality of our manufacturing and preclinical work. We are continuing our dialogue with regulators broadly as we continue to evaluate all financing options, including partnering discussions, for the Phase 3 trial."

Results from the SCOPE Phase 2 trial have enabled Scancell to select iSCIB1+, administered needle-free intramuscularly, for further development in patients with selected human leukocyte antigen (HLA) alleles, representing 80% of melanoma patients. This profile is reflected within Cohort 3 of the SCOPE trial.

Updated data in this cohort show PFS was 74% at 16 months in the target population. This compares favourably to PFS reported with ipilimumab plus nivolumab alone, the current standard of care, of 50% at 11.5 months[1]. The favourable PFS remains consistent across key subgroups analysed including PD-L1 low, BRAF Wildtype and prior checkpoint inhibitor exposure, who might be expected to have worse outcomes.

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

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SCOPE (ClinicalTrials.gov: NCT04079166) is a Phase 2, UK multi-centre open-label study investigating SCIB1/iSCIB1+ in combination with checkpoint inhibitors in late-stage melanoma and enrolling 140 patients across four cohorts. Its aim is to evaluate the efficacy, safety and durability of SCIB1 or iSCIB1+ DNA Immunobody® therapies when given to patients in combination with SoC checkpoint inhibitors in stage IIIB/IV unresectable metastatic melanoma, and to define the parameters to design a Phase 3 randomised registration trial.

Scancell (LSE:SCLP; www.scancell.co.uk) is a clinical stage biotechnology company developing targeted off-the-shelf active immunotherapies, to generate safe and long-lasting tumour-specific immunity for a cancer-free future. iSCIB1+, the lead product from their DNA ImmunoBody® platform has demonstrated safe, durable and clinically meaningful benefit as a monotherapy as well as additional benefit when combined with checkpoint therapies in a Phase 2 trial in melanoma. Modi-1, the lead peptide immunotherapy from their Moditope® platform, is being investigated in a Phase 2 study in a broad range of solid tumours. In addition, Scancell's wholly owned subsidiary, GlyMab Therapeutics Ltd., has been established with the intention to hold and develop an exciting early-stage pipeline of high affinity GlyMab® antibodies targeting tumour specific glycans, two of which already have been licensed and are being developed by Genmab A/S, an international biotechnology company and global leader in the antibody therapeutics space.

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[1] Ipilimumab and Nivolumab in Checkmate 06

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