28th April 2026

Scancell Holdings plc

Scancell receives FDA Fast Track Designation for iSCIB1+ in advanced melanoma and provides data update from its SCOPE Phase 2 study

Potent and durable efficacy with iSCIB1+ of 77% progression free survival (PFS) at 20 months, in combination with ipilimumab and nivolumab, demonstrated in the Phase 2 SCOPE trial; more PFS and additional early overall survival (OS) data expected in H1 2027

Initiation of the registrational Phase 3 trial with iSCIB1+ in advanced melanoma anticipated in H2 2026

Scancell Holdings plc (AIM: SCLP), the developer of active immunotherapies to treat cancer, announces that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its lead ImmunoBody® iSCIB1+ for the treatment of advanced melanoma.

Dr Phil L'Huillier, CEO of Scancell, said: "This designation is a major achievement for Scancell and important recognition not only of the potential of iSCIB1+, but also of the significant need for new and improved treatment options for patients with advanced melanoma. We are very pleased with how the Phase 2 SCOPE data is maturing and are advancing plans for a global registrational Phase 3 trial, which we expect to initiate in the second half of 2026."

Progression free survival (PFS) has matured positively, reaching 77% at 20 months in the target population[1]. This widens the lead of iSCIB1+ over PFS reported with ipilimumab plus nivolumab alone of 43% at 20 months, now representing a 30+ percentage point improvement over standard of care (SoC).[2]

The Fast Track Designation is granted for investigational therapies that show advantage over available treatments, such as superior effectiveness, and provides the process to expedite review of drugs for serious conditions, with the aim of getting effective therapies to patients faster. The designation enables frequent engagement to ensure alignment on development plans, enhance development predictability and support a more efficient path through clinical development. Moreover, Fast Track Designation brings eligibility for Accelerated Approval, Priority Review and Rolling Review.

Additional PFS data and early OS data from the Phase 2 SCOPE study are expected in H1 2027.

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[1]The target population represents patients with human leukocyte antigen (HLA) alleles present in approximately 80% of melanoma patients in the SCOPE trial's third cohort, which also represents the population to be selected in the Company's upcoming Phase 3 trial.

[2] SoC represents the combination of ipilimumab and nivolumab measured using the results of the pivotal Checkmate 067 trial

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

-ENDS-

About the SCOPE Phase 2 study

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 11 doses of either SCIB1 or iSCIB1+ using the PharmaJet 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 **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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