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Scancell reports Phase 2 data showing strongly improved outcomes in Late-Stage Melanoma with its Immunobody® iSCIB1+

SCOPE trial of SCIB1/iSCIB1+ plus standard of care shows excellent results encompassing efficacy, durability, immune responses and safety

Overall response rate for iSCIB1+ was 69% for target HLA type patients, representing 80% of total patients - greatly exceeding the 48-50% for standard of care

12-month progression-free survival also markedly improved, with a 20% increase over standard of care

iSCIB1+ Immunobody® selected for future development; planning for registrational Phase 2b/3 global study accelerated

Data provides option for patient selection biomarker for future registrational study

Scancell to host presentation and Q&A on data at 13:00 BST

Scancell Holdings plc (AIM: SCLP), the developer of Immunobody® and Moditope® active immunotherapies to treat cancer, announces further positive data from the ongoing Phase 2 SCOPE trial of SCIB1/iSCIB1+ Immunobody® DNA active immunotherapies in combination with checkpoint inhibitors in patients with advanced unresectable melanoma. The data demonstrates a potential new benchmark for treatment of patients with late-stage melanoma in terms of efficacy, durability, immune responses and safety.

Dr Heather Shaw, lead for the Medical Oncology Skin Cancer Service at University College London Hospital, London and principal investigator of the SCOPE trial, said: *"The addition of SCIB1 or iSCIB1+ to standard-of-care checkpoint inhibitors has demonstrated extremely exciting early signals, including improved overall response rates and progression-free survival to date, without a meaningful increase in treatment-related toxicity. These findings highlight the real potential for a significant clinical benefit for patients with advanced melanoma, where there is an unmet need. As the progression-free survival and overall survival data matures, expediting the planned registrational randomised controlled trial will be critical. This study will have the potential to redefine current treatment paradigms for a disease that remains challenging for many patients."*

Patients in Cohorts 1 and 3 received SCIB1 or iSCIB1+, respectively, in combination with ipilimumab and nivolumab, the current standard of care ("SoC"). The combined overall response rate ("ORR") for evaluable patients in Cohorts 1 and 3 was 68.6% (46 out of 67 patients), with a disease control rate ("DCR") of 88.0% and complete response rate ("CR") of 17.9% (12 out of 67 patients). Cohort 2 evaluating SCIB1 in combination with pembrolizumab showed comparable results in the 9 target patients after the cohort was stopped due to the change in SoC in the UK. These results represent a substantial improvement over the previously reported ORR for ipilimumab + nivolumab of 50% in the Checkmate 067 study and about 48% in the real-world setting*.

Cohort 1 achieved 12-month progression-free survival ("PFS") of 64.6%, and Cohort 3 demonstrated 11-month PFS of 80.8%. These compare favorably to previously reported PFS of 43.9% for ipilimumab plus nivolumab at 12 months*. The safety profiles of the SCIB1/ iSCIB+ combinations with SoC were consistent with that seen previously with the ipilimumab and nivolumab combination alone, suggesting the Immunobody® therapy did not add any safety issues and is well tolerated.

Dr Nermeen Varawalla, Chief Medical Officer of Scancell, said: *"iSCIB1+ has shown meaningful benefits in terms of responses, disease control, progression-free survival and immune responses, which offer a potentially huge improvement for patients. Furthermore, its strong safety profile suggests that iSCIB1+ could be used in addition to SoC without adding toxicities. These data demonstrate the potential of iSCIB1+ in patients with metastatic melanoma as well as highlight the significant potential in earlier stage resectable disease when administered in the neoadjuvant / adjuvant setting. The results also provide the option of a biomarker to predict responders which could be a significant advantage in selecting participants in a future registrational study."*

The recent updated data showed that all six epitopes in the DNA Immunobody® therapy iSCIB1+, generated targeted T cell responses. CD8 T cell responses were associated with an improved clinical response rate of 83%. These T cells both kill tumor cells and induce memory T cells, resulting in a deep and prolonged response. The CD8 T cell response could be predicted using the human leukocyte antigen ("HLA") class I alleles which in turn could be a patient selection biomarker. This next-generation Immunobody® iSCIB1+, includes additional epitopes targeting HLA class 1 alleles present in 80% of the population, has improved avidity from Scancell's AvidiMab® platform, and showed equipotency and equal safety compared to SCIB1. iSCIB1+ is efficacious in a wider patient population than SCIB1, 80% compared with 40% for SCIB1 and is therefore the candidate of choice for further development. This rapid development of iSCIB1+ demonstrates the potential of Scancell's technology platforms for continuous product refinement and improvement so as to provide greater benefits for larger numbers of patients. The SCOPE study also provides Scancell with the option of a patient selection biomarker for a future registrational study.

Dr Phil L'Huillier, CEO of Scancell, said: *"These data demonstrate that we can add iSCIB1+ to the combination of nivolumab and ipilimumab, or potentially combine it with pembrolizumab, to produce a marked benefit for patients with advanced melanoma. In the US alone, ipilimumab plus nivolumab has a market share of 65-70% of metastatic melanoma patients. We have selected iSCIB1+ for further development and are now accelerating our planning for a global registrational study in the advanced melanoma setting and assessing the potential of a second trial in earlier lines of disease. We expect to engage with the U.S. Food and Drug Administration on the design of this trial ahead of reporting interim data from Cohort 4, which we expect around the year end."*

SCOPE (NCT04079166) is a Phase 2, UK multi-centre open-label study investigating SCIB1/iSCIB1+ in combination with checkpoint inhibitors in late-stage melanoma and will enroll more than 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 inform the design of a Phase 2b/3 randomized controlled registration trial.

randomized controlled registration trial.

Scancell will host a presentation on the SCOPE data, followed by a Q&A with management, on 22 July at 13:00 BST. Please click here to register for the call.

*European Journal of Cancer 2022 (Serra-Bellver et al)

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

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SCIB1 is the lead product from the Company's DNA Immunobody® platform, which uses the body's immune system to identify, attack and destroy tumors. 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.

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 tumor-specific immunity for a cancer-free future. iSCIB1/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 an ongoing 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 tumors. In addition, Scancell's wholly-owned subsidiary, Glymab Therapeutics Ltd., is developing an exciting early-stage pipeline of high affinity GlyMab® antibodies targeting tumor 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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