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Scancell Holdings Plc
("Scancell" or the "Company")

Peer-reviewed publication highlights potential of SCIB1 therapy for melanoma patients

Compelling 5-year survival data with most resected stage III and IV patients remaining alive

Phase 2 trial anticipated to start in H2 2018

Scancell Holdings plc, ('Scancell' or the 'Company') the developer of novel immunotherapies for the treatment of cancer, is pleased to announce the publication of a peer-reviewed research paper in the scientific journal *OncoImmunology* entitled: "Targeting gp100 and TRP-2 with a DNA vaccine: incorporating T cell epitopes with a human IgG1 antibody induces potent T cell responses that are associated with favourable clinical outcome in a Phase 1/2 trial". The Company also provides an update on current survival data along with its future plans for a US clinical trial in patients with malignant melanoma.

The publication describes the outcome of the Company's Phase 1/2 clinical trial of SCIB1 in patients with malignant melanoma up to the date when all patients had received five doses of SCIB1 in the main part of the study. The paper concludes that "SCIB1 is a novel class of anti-cancer immunotherapy that induces T cells which can cause tumour regression in patients with melanoma. The high frequency of responses, their breadth and durability suggest that SCIB1 is worthy of further study in a larger cohort of patients. This is particularly the case in the adjuvant setting, where all of the patients responded immunologically and where absence of toxicity is an important clinical consideration. Furthermore, the stimulation of potent *de novo* immune responses by SCIB1 may provide an opportunity for synergistic combination therapy with checkpoint inhibitors in late stage disease." The full abstract of the paper can be found below.

SCIB1 ongoing survival data

Since the cut-off date for the publication, the Company has continued to collect survival data for the trial patients and, as of February 2018, SCIB1 continues to deliver increasingly impressive results:

- Overall, 18 of 20 stage III/IV melanoma patients with resected disease remain alive.
- Of the 16 resected patients who received 2-4 mg doses of SCIB1, only six patients have had recurrence of their disease with only two deaths.
- All 14 surviving patients in this group have passed the five year time point since study entry. The four patients who had disease recurrence went on to receive other treatments for their melanoma. However, despite having received multiple interventions and recurrences prior to study entry, the other 10 patients had no treatment other than SCIB1.
- One patient with unresected disease has also survived for more than five years since starting treatment with SCIB1 despite disease progression.*
- Two of four resected patients who received 8 mg doses of SCIB1 have experienced disease recurrence although none have died.* The median observation time for this group of patients is currently 35 months.

*All patients who relapsed went on to receive additional therapies for their melanoma

SCIB1 US IND and Phase 2 study

The Company's Investigational New Drug (IND) application for SCIB1 is expected to be filed with the Food and Drug Administration (FDA) during the first half of 2018. Following the pre-IND meeting in 2017, the FDA suggested that technical data from Ichor's new TriGrid 2.0 clinical device should be submitted 30-60 days prior to Scancell's own FDA submission. Ichor has now submitted the required data to the FDA, and therefore, subject to funding, patient enrolment into this trial is now expected to commence in the second half of 2018.

The study, which will be a Phase 2 checkpoint inhibitor combination study with SCIB1 in patients with advanced melanoma, will be led by Principal Investigator Dr Keith Flaherty, Director of the Termeer Center for Targeted Therapy at Massachusetts General Hospital and Associate Professor at Harvard Medical School.

Dr Keith Flaherty commented: "Although the checkpoint inhibitors have improved the prognosis for many melanoma patients, a significant proportion of patients do not respond to these new regimes. The combination of SCIB1 with a checkpoint inhibitor may significantly expand the population of patients who benefit from immunotherapy."

Dr Cliff Holloway, CEO of Scancell, said: "We are delighted to see the data from our Phase 1/2 study published in the respected peer-reviewed journal *OncoImmunology*. The continuing survival of these patients is impressive as many had undergone multiple resections of their tumours prior to SCIB1 treatment but have had no evidence of any further disease recurrence. This compares extremely favourably with checkpoint inhibitors, but has the advantage of being associated with significantly less toxicity. We remain on track to submit an IND to enable our Phase 2 study combining SCIB1 with a checkpoint inhibitor to start in the second half of this year."

Abstract

Targeting gp100 and TRP-2 with a DNA vaccine: incorporating T cell epitopes with a human IgG1 antibody induces potent T cell responses that are associated with favourable clinical outcome in a phase 1/2 trial

A DNA vaccine, SCIB1, incorporating two CD8 and two CD4 epitopes from TRP-2/gp100 was evaluated in patients with metastatic melanoma. Each patient received SCIB1 via intramuscular injection with electroporation. The trial was designed to find the safest dose of SCIB1 which induced immune/clinical responses in patients with or without tumour. Fifteen patients with tumour received SCIB1 doses of 0.4-8 mg whilst 20 fully-resected patients received 2-8 mg doses. Twelve patients elected to continue immunization every 3 months for up to 39 months. SCIB1 induced dose-dependent T cell responses in 88% of patients with no serious adverse effects or dose limiting toxicities. The intensity of the T cell responses was significantly higher in patients receiving 4 mg doses without tumour when compared to those with tumour ($p< 0.01$). In contrast, patients with tumour showed a significantly higher response to the 8 mg dose than the 4 mg dose ($p< 0.03$) but there was no significant difference in the patients without tumour. One of 15 patients with measurable disease showed an objective tumour response and 7/15 showed stable disease. 5/20 fully-resected patients have experienced disease recurrence but all remained alive at the cut-off date with a median observation time of 37 months. A positive clinical outcome was associated with MHC-I and MHC-II expression on tumors prior to therapy ($p=0.027$). We conclude that SCIB1 is well tolerated and stimulates potent T cell responses in melanoma patients. It deserves further evaluation as a single agent adjuvant therapy or in combination with checkpoint inhibitors in advanced disease.

Poulam M Patel, Christian H Ottensmeier, Clive Mulatero, Paul Lorigan, Ruth Plummer, Hardev Pandha, Somaia Elsheikh, Efthymios Hadjimichael, Naty Villasanti, Sally E Adams, Michelle Cunnell, Rachael L Metheringham, Victoria A Brentville, Lee Machado, Ian Daniels, Mohamed Gijon, Drew Hannaman & Lindy G Durrant. Oncolmmunology; accepted author version posted online: 01 Feb 2018.

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About Scancell

Scancell is developing novel immunotherapies for the treatment of cancer based on its ImmunoBody® and Moditope® technology platforms.

Scancell's first ImmunoBody®, SCIB1 is being developed for the treatment of melanoma. Data from the Phase 1/2 clinical trial demonstrate that SCIB1, when used as monotherapy, has a marked effect on tumour load, produces a melanoma-specific immune response and highly encouraging survival trend without serious side effects. In patients with resected disease there is increasing evidence to suggest that SCIB1 may delay or prevent disease recurrence.

Scancell's ImmunoBody® vaccines target dendritic cells and stimulate both parts of the cellular immune system: the helper cell system where inflammation is stimulated at the tumour site and the cytotoxic T-lymphocyte or CTL response where immune system cells are primed to recognise and kill specific cells.

Pre-clinical data on a combination of SCIB1 or SCIB2 and checkpoint inhibition (blockade of the PD-1 or CTLA-4 immune checkpoint pathways) have shown enhanced tumour destruction and significantly longer survival times than when either treatment was used alone. Experimental data suggests that the high avidity T cells induced by ImmunoBody® vaccines increase expression of PDL-1 on the tumour cell surface, thereby making the tumours more sensitive to checkpoint inhibitor drugs. Re-challenging animals with tumour cells after SCIB1 treatment resulted in 100% survival suggesting that ImmunoBody® induces a powerful memory response. Such an effect has not been observed with checkpoint inhibitors.

Scancell has also identified and patented a series of modified epitopes that stimulate the production of killer CD4+ T cells that destroy tumours without toxicity. The Directors believe that the Moditope® platform could play a major role in the development of safe and effective cancer immunotherapies in the future.