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Ichor partner Scancell Announces Update on SCIB1 Phase 1/2 clinical trial

Preliminary evidence of immune response and clinical benefit

Scancell Holdings Plc, (AIM:SCLP), the developer of therapeutic cancer vaccines, is pleased to announce preliminary results from Part 1 of the Phase 1/2 clinical trial of its DNA ImmunoBody® vaccine in patients with Stage III/IV malignant melanoma. Of the six patients allocated to the 2mg and 4mg dose cohorts and who received at least four doses of SCIB1, four have shown a vaccine-induced T cell response to treatment.

Although the study was not designed primarily to measure tumour response, one patient in the 4mg dose cohort with multiple tumour lesions at study entry had a differential response to treatment including partial or complete regression of all lung metastases. A further two patients who had all their tumours surgically removed prior to SCIB1 treatment have remained disease-free more than a year after first dosing. The vaccine produced very few side effects, none of which were serious.

These encouraging results provide the first evidence that Scancell's ImmunoBody® vaccine approach is producing an immune response in cancer patients which may also be associated with clinical benefit. In view of the positive results and minimal side effects seen with the 4mg dose the Company intends to evaluate an 8mg dose in parallel with Part 2 of the Phase1/2 study.

The first part of this Phase 1/2 clinical trial was conducted in five UK centres in 11 patients, ten with stage IV and one with Stage III malignant melanoma. Patients were to be given five doses of 0.4mg, 2mg or 4mg of SCIB1, delivered by Ichor Medical Systems' TriGrid™ electroporation delivery device, over a period of six months. One patient in the 0.4mg dose group and one in the 4mg dose group who received only a single dose of SCIB1 were withdrawn from the study due to progressive disease shortly after study entry and were replaced to ensure that at least three patients in each dose cohort could be fully evaluated for immune response. During the course of the study regulatory approval was granted to increase the SCIB1 dose from 2mg to 4mg in patients in the 2mg cohort, if the vaccine was well tolerated. Two patients in this group received two 4mg doses of SCIB1 and one patient received a single 4mg dose.

Clinical response

Three of the four patients in the 4mg cohort are still alive and one remains disease-free more than a year after starting treatment. The fourth patient progressed and died too soon after first dosing for any effect to be seen. Two out of the three patients in the 2/4mg cohort are still alive and one remains disease-free more than a year after starting treatment. The third patient died of progressive disease after 63 weeks. Three out of four patients in the 0.4mg dose group have died. The fourth patient is still alive 27 months after starting treatment.

One patient in the 4mg dose group had a long history of metastatic disease and multiple tumour lesions present at the start of treatment (including several in her lungs), all of which decreased in size or disappeared completely following six months of treatment with SCIB1 except for one abdominal tumour nodule which increased in size and which will be resected. This "differential response" pattern is typical of immunotherapeutic agents and is the first signal that SCIB1 may be having an impact on the course of the disease as well as inducing an immune response.

Two further patients on SCIB1 remain disease-free more than one year after treatment started. The first patient had a history of gradual disease progression in the six months prior to study entry, including the development of multiple tumour nodules, which were excised prior to study treatment. This patient was dosed five times with 4mg SCIB1 and had no tumour present at study entry so could not be evaluated for

tumour response but is still disease-free 15 months after first dosing and 18 months after the last tumour surgery. The second patient (in the 2/4mg cohort), who also received two 4mg doses at three and six months after the start of dosing, was entered into the study after all recurrent tumour had been resected and remains disease–free, 17 months after first dosing and 23 months after the last tumour excision. Whilst these results are promising it should be emphasised that they will have to be confirmed in larger, controlled studies in due course

Immune response

All three patients in the 2/4mg dose cohort and one patient in the 4mg dose cohort produced an immune response to the melanoma specific epitopes in SCIB1. Only one of the patients in the lowest dose group showed any immune response to treatment.

Immune response was measured by peptide-specific proliferation that was at least twice the background control at each time point and at least twice the pre-treatment control value on two or more of the six time points measured. The patient with the differential clinical response was also assessed using a cultured enzyme-linked immunosorbent (ELISPOT) assay and made a strong response to the melanoma TRP-2 antigen.

These preliminary results suggest that therapeutic vaccination with SCIB1 induces specific immune responses that may lead to clinical benefit. In view of the positive results and minimal side effects seen with the 4mg dose the Company intends to evaluate an 8mg dose in a further cohort of three to six patients with evaluable disease, thereby permitting an assessment of the safety and immunogenicity of an increased dose of SCIB1 in addition to the effect of this higher dose on tumour burden. This additional cohort will be evaluated in parallel with the second part of the Phase 1/2 study which is primarily designed to assess the effect of the 4mg dose on immune response in patients who have had all tumour removed prior to treatment.

Prof Lindy Durrant, Joint CEO of Scancell Holdings and Professor of Cancer Immunotherapy at Nottingham University, commented: "*These preliminary results show for the first time that Scancell's ImmunoBody® vaccine, SCIB1, can elicit melanoma-specific immune responses in patients that appear to be associated with clinical benefit and provides clinical validation for the ImmunoBody® approach. The assessment of a higher dose in patients with evaluable disease and the further assessment of immune responses in Part 2 of the Phase 1/2 trial should provide further evidence to support the use of ImmunoBody® vaccines for the treatment of cancer*".

Prof Poulam Patel, Principle Investigator and Prof of Clinical Oncology at the University of Nottingham, commented: " *I am pleased that we have successfully completed the first part of this study and that we have seen measurable immune responses in patients. I am particularly interested in the shrinkage of the tumours we have seen in a patient with lung secondaries and look forward to seeing the results of the next part of the study,"*

Bob Bernard, President and CEO of Ichor, commented: "*We are happy to see the progress of our partner, Scancell Holdings, in advancing their DNA ImmunoBody® SCIB1 cancer vaccine with our enabling TriGrid delivery system*."

Leading oncologist Karol Sikora, Professor of Cancer Medicine and external assessor to Scancell commented: *"The positive immune response data and impressive clinical response in the patient with multiple lung metastases is encouraging news for patients with malignant melanoma. The temporal relationship of the disappearance of the lung metastases in this patient is very suggestive of the effective immune destruction of the cancer. I look forward to seeing the results of the ongoing studies and in particular whether a higher dose of SCIB1 will confirm the impact of SCIB1 on active disease."*

Dr Richard Goodfellow, Joint CEO of Scancell Holdings, commented: " *This is a defining moment for Scancell. These preliminary yet encouraging results provide the first clinical endorsement for the groundbreaking cancer vaccine research undertaken by Scancell under the scientific leadership of Prof Durrant. We will continue to gather additional longer term data on these patients and those in Part 2 of the study during 2013."*

The Directors of the issuer accept responsibility for this announcement.

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The design of the Phase 1/2 study

Part 1 of this Phase1/2 clinical trial was conducted in five UK centres in 11 patients with Stage III/IV malignant melanoma. Patients were to be given five doses of 0.4mg, 2mg or 4mg of SCIB1, delivered using the Ichor Medical Systems' TriGrid™ electroporation delivery device, over a period of six months at the start of the trial, as well as at three weeks, six weeks, three months, and six months after the initial dose.

As this was the first human trial of SCIB1, safety of each dose was assessed before patients were given a higher dose.

In view of the positive results and minimal side effects seen with the 4mg dose the Company intends to evaluate an 8mg dose in parallel with Part 2 of the Phase1/2 study.

Part 2 of the study is being conducted in 13 patients with resected Stage III/IV disease and is designed to further assess the cellular immune response, safety and tolerability of the 4mg dose when given over a period of 6 months.

About SCIB1

SCIB1 is a plasmid DNA which encodes a human antibody molecule engineered to express a melanoma antigen called Tyrosinase-Related Protein 2 (TRP2) plus two helper T cell epitopes. Following immunisation, the engineered antibody will be expressed and be taken up by dendritic cells, resulting in the development of immune responses against tumour cells expressing the TRP2 antigen.

SCIB1 was designed so that the Fc component of the engineered antibody will be recognised by the high affinity CD64 receptor present on dendritic cells, leading to a significant enhancement of both the frequency and avidity of the T cell immune response. The induction of high avidity T cells against TRP-2 is expected to lead to the inhibition and regression of both primary and metastatic tumour growth.

About ImmunoBody®

An ImmunoBody® is a human antibody or fusion protein engineered to express helper cell and CTL epitopes from tumour antigens over-expressed by cancer cells. Antibodies are ideal vectors for carrying T cell epitopes from tumour antigens as they have long half-lives and can effectively target dendritic cells via their Fc receptors, allowing efficient stimulation of both helper and CTL responses.

The Immunobody® technology can be adapted to provide the basis for treating any tumour type and may also be of potential utility in the development of vaccines against hepatitis, HIV and other chronic infectious diseases.

About Scancell

Scancell is developing therapeutic vaccines for the treatment of cancer and infectious diseases based on its ImmunoBody® and Moditope™ technology platforms. Scancell's first cancer vaccine SCIB1 is being developed for the treatment of melanoma and is in Phase 1/2 clinical trials.

Treating cancer by vaccination allows small non-toxic doses of a vaccine to be administered to a patient, stimulating an immune response. Effective cancer vaccines need to target dendritic cells to 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.

A limitation of many cancer vaccines currently in development is that they cannot specifically target dendritic cells in vivo. Several groups have demonstrated successful vaccination by growing dendritic cells ex vivo, pulsing them with tumour antigens and re-infusing them. However, this procedure is patient specific, time consuming and expensive. Scancell has developed its breakthrough patent protected ImmunoBody® technology to overcome these limitations.

Scancell has also identified and patented a series of modified epitopes that stimulate the production of killer CD4 that destroy tumours without toxicity. The Directors believe that the Moditope™ platform could have a profound effect on the way that cancer vaccines are developed.

About Ichor Medical Systems

Ichor Medical Systems' TriGrid™ Delivery System (TriGrid) is the first integrated and fully automated device for electroporation-mediated DNA administration in humans. Ichor, a privately-held biotech company based in San Diego, CA, is collaborating with partners to provide its enabling TriGrid platform as a means for delivery of DNA drugs and vaccines in disease indications such as melanoma, malaria, hepatitis B virus (HBV) infection, human immunodeficiency virus (HIV) infection, melanoma, Alzheimer's disease, and others. For further information, visit www.ichorms.com.