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Scancell Holdings plc
(“Scancell” or the “Company”)

Scancell announces positive response in COVIDITY trial

COVIDITY vaccine candidates induce neutralising antibody and T cell responses in naïve participants and boost responses in previously vaccinated / infected participants

The trial validates that AvidiMab®-modified immunotherapies boost immune responses and PharmaJet’s needle-free injection device is effective in delivering ImmunoBody®-generated drug candidates

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer and infectious disease, today announces preliminary immunogenicity data from its Phase 1 COVIDITY clinical trial which was conducted at the University of Cape Town (UCT) Lung Institute in South Africa. The objectives of the trial were to assess the safety and immunogenicity of two vaccine candidates, SCOVI and SCOV2, in healthy, vaccine-naïve subjects, prior to testing the candidates as a booster in SARS-CoV-2 pre-infected or pre-vaccinated volunteers. SCOVI and SCOV2 are both plasmid DNA vaccines based on the Company’s ImmunoBody® technology and incorporate its AvidiMab® modifications to further enhance the immune responses induced following vaccination.

The data from the Phase 1 COVIDITY trial showed that neutralising antibodies were induced as well as T cell responses to both the receptor binding domain (RBD) of the spike protein and the nucleocapsid antigen (NCAP). In vaccine-naïve subjects, the seroconversion rate (the level of detectable antibodies in the blood due to vaccination) was 67% following SCOVI/SCOV2 vaccination, with a broad reactivity against multiple COVID-19 variants, including the currently dominant Omicron variant. These positive results demonstrate that SCOVI and SCOV2, delivered via PharmaJet’s needle-free injection device, induce immune responses in naïve participants. Additionally, a single dose of SCOV2 boosted broad responses in previously exposed subjects.

As previously disclosed, the Board of Scancell have decided not to take this vaccine forward in house due to the large size of later stage trials and the competitive Covid-19 landscape, however the positive data for COVIDITY demonstrates the validation of the vaccine platform, including AvidiMab®. As a result, the Company will now seek a partner to progress the COVIDITY vaccine programme. In addition, the success of the vaccine administration using PharmaJet’s needle-free injection devices in the COVIDITY trial provides rationale for the Company to further incorporate the device in future trials.

Honorary Prof Rod Dawson, Managing Director of the University of Cape Town Lung Institute, commented:

“We are delighted to report the positive immune response data from the COVIDITY trial. 66 participants were immunised with SCOVI, targeting the original A lineage of SARS-CoV-2 and/or SCOV2, targeting the Beta variant of concern. The results from the trial were highly encouraging, inducing neutralising antibody and T cell responses with no safety concerns.”

Prof Lindy Durrant, Chief Executive Officer, Scancell, commented:

“These results are highly encouraging. Not only do they provide clinical proof of concept for the COVIDITY COVID-19 vaccine programme itself, more broadly they also provide important further validation and learnings for Scancell’s ImmunoBody® and AvidiMab® platforms. The success of a human trial demonstrating that an AvidiMab® modified DNA vaccine, delivered via a needle free injection, can induce both T cell and antibody responses, with no safety concerns, is a pivotal proof point for Scancell’s clinical strategy.

“Further large studies would be required to confirm the potential of the COVIDITY vaccine candidates to stimulate broad, cross-variant reactivity and compete with the currently approved COVID-19 vaccines. Therefore, and as previously disclosed, the Board has decided to seek a partner to further progress this programme. Going forwards, Scancell will focus its resources on progressing the portfolio of innovative immuno-oncology drug candidates that we have generated from our platforms.”

About the data

The initial COVIDITY Phase 1 study design was to dose healthy, vaccine-naïve subjects with two vaccinations of SCOVI to demonstrate safety, followed by two vaccinations of SCOV2 to specifically induce responses

against the Beta variant that was prevalent in South Africa at the time the study started. Twenty-two subjects were recruited and randomised to receive injections via either intradermal or intramuscular needle-free injection using a PharmaJet device. Thirteen of the vaccine-naïve subjects were seronegative at screening (indicating they had not had a previous COVID-19 infection) and nine were seropositive (indicating a previous infection); however, a surge of Omicron infections throughout South Africa resulted in most subjects becoming infected before they could generate a vaccine-specific immune response. However, three seronegative participants completed all four immunisations without becoming infected with COVID-19; two subjects had vaccine-specific T cell responses specific to RBD and/or NCAP, and two had a four-fold increase in RBD neutralising antibodies.

To enable testing of the COVIDITY vaccine in a real-world setting, the protocol was amended to include SCOVID2 boosting of volunteers who had previously been infected with SARS-CoV-2, irrespective of their vaccination status, or volunteers who were vaccinated but not infected with SARS-CoV-2. 44 subjects were recruited, 41 of whom were seropositive at screening and, as such, had pre-existing T cell responses specific to RBD and NCAP, with correspondingly high neutralising antibody titres. Following vaccination with SCOVID2, 51% of participants who remained COVID-free during the trial showed a further doubling in their RBD-specific T cell response and 26% showed a further doubling of their NCAP-specific T cell response. RBD neutralising antibody titres against the Beta variant doubled in 44% of subjects and NCAP antibody titres doubled in 42% of participants. Of particular interest was that the RBD neutralising antibody responses induced by SCOVID2 cross-reacted with the Wuhan (A lineage), Gamma, Delta and Omicron variants. The responses seen were similar irrespective of the route of administration, both SCOVID1 and SCOVID2 were well tolerated, there were no severe adverse events reported during the study and the needle-free administration was well received.

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

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About Scancell

Scancell is a clinical stage biopharmaceutical company that is leveraging its proprietary research, built up over many years of studying the human adaptive immune system, to generate novel medicines to treat significant unmet needs in cancer and infectious disease. The Company is building a pipeline of innovative products by utilising its four technology platforms: Moditope[®] and ImmunoBody[®] for vaccines and GlyMab[®] and AvidiMab[®] for antibodies.

Adaptive immune responses include antibodies and T cells (CD4 and CD8), both of which can recognise damaged or infected cells. In order to destroy such cancerous or infected cells, Scancell uses either vaccines to induce immune responses or monoclonal antibodies (mAbs) to redirect immune cells or drugs. The Company's unique approach is that its innovative products target modifications of proteins and lipids. For the vaccines (Moditope[®] and ImmunoBody[®]) this includes citrullination and homocitrullination of proteins, whereas its mAb portfolio targets glycans or sugars that are added onto proteins and / or lipids (GlyMab[®]) or enhances the potency of antibodies and their ability to directly kill tumour cells (AvidiMab[®]).

For further information about Scancell, please visit: <https://www.scancell.co.uk/>