19 August 2019

**Scancell Holdings plc**
("Scancell" or the "Company")

**Update on the SCIB1 Phase 2 clinical trial in patients with advanced melanoma**

*Initiation of patient enrolment into UK sites*

Scancell, the developer of novel immunotherapies for the treatment of cancer, today announces the initiation of and further updates on the SCIB1 Phase 2 trial in patients with metastatic melanoma also receiving the checkpoint inhibitor pembrolizumab (Keytruda).

As reported in April, the Company has received the necessary regulatory and ethical approvals to initiate the UK arm of the SCIB1 clinical trial. Operational activities for clinical centre initiation in the UK have now been completed. In the US, the Food and Drug Administration ("FDA" or the "Agency") requested additional information from Ichor Medical Systems ("Ichor") on the TriGrid® 2.0 electroporation delivery system. Whilst there has been extensive dialogue between Ichor and the Agency, a timely resolution to the device-specific questions has yet to be agreed.

In order to initiate patient recruitment in the UK under the Investigational New Drug (IND) application submitted to the Agency, prior approval of the IND is required. Having considered the ethical issues related to patients awaiting enrolment into the UK sites, Scancell has decided to withdraw its IND application in the US to allow the UK arm of the trial to proceed.

Scancell will resubmit the IND at a later date with the intent to initiate clinical sites in the US, following further clarification from the Agency regarding Ichor's TriGrid® 2.0 delivery device.

The Phase 2 study is designed to assess whether the addition of SCIB1 to pembrolizumab will result in an improvement in the tumour response rate, progression-free survival and overall survival in 25 patients with advanced melanoma, who are also eligible for treatment with pembrolizumab. Professor Poulam Patel, Chief Investigator for the SCIB1 Phase 1/2 clinical trial and Professor of Clinical Oncology at the University of Nottingham, will now be the Chief Investigator for the Phase 2 study. Patient enrolment into the UK arm of the study will commence immediately.

Dr Cliff Holloway, Chief Executive Officer, Scancell, commented:

*"We are pleased to be able to advance our SCIB1 Phase 2 trial in the UK as we believe that SCIB1 administration with an immune checkpoint inhibitor such as pembrolizumab has the potential to offer greater efficacy than when either agent is used alone. Whilst it is disappointing that discussions in the US have taken longer than anticipated, we will continue our dialogue with both Ichor and the Agency, and plan to resubmit the IND as soon as possible."*

Professor Poulam Patel, Chief Investigator, commented:

*"There remains an urgent need for improved therapies in melanoma. Based upon our previous successful trial with SCIB1 alone we are excited to see if the addition of SCIB1 to current, standard treatment with pembrolizumab increases our anti-cancer response rate."*

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

**For Further Information:**


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**About Scancell**

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

ImmunoBody® vaccines target dendritic cells and stimulate both parts of the cellular immune system. They have the potential to be used as monotherapy or in combination with checkpoint inhibitors and other agents. This platform has the potential to enhance tumour destruction, prevent disease recurrence and extend survival.

- SCIB1, the lead programme, is being developed for the treatment of melanoma. A phase 1/2 clinical trial has so far successfully demonstrated survival data of more than five years.

- SCIB2 is being developed for the treatment of non-small cell lung cancer and other solid tumours. Scancell has entered into a clinical development partnership with Cancer Research UK (CRUK) for SCIB2.

Moditope® represents a completely new class of potent and selective immunotherapy agents based on stress-induced post-translational modifications (siPTM). It stimulates the production of killer CD4 T cells which overcome the immune suppression induced by tumours, allowing activated T cells to seek out and kill tumour cells that would otherwise be hidden from the immune system. Moditope® alone, or in combination with other agents, has the potential to treat a wide variety of cancers.

- Modi-1 is being developed for the treatment of solid tumours including triple negative breast cancer, ovarian cancer and head and neck cancer.

For further details, please see our website: www.scancell.co.uk