

3 February 2020

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

## **SCIB1 Investigational New Drug (IND) application approved**

*Phase 2 clinical trial to commence in the US*

Scancell, the developer of novel immunotherapies for the treatment of cancer, is pleased to announce that the Investigational New Drug (IND) application to the Food and Drug Administration (FDA) for SCIB1 has been approved. As a result, Scancell will initiate the US arm of the Phase 2 clinical trial of SCIB1 in patients with metastatic melanoma also receiving the checkpoint inhibitor pembrolizumab (Keytruda), using Ichor's TriGrid® 2.0 electroporation 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. Patient screening was initiated in the UK, with Professor Poulam Patel, Professor of Clinical Oncology at the University of Nottingham as the Chief Investigator for the global study. US site initiation activities and patient enrolment will commence alongside clinical site expansion in the UK.

Dr Keith Flaherty, Professor of Medicine at Harvard Medical School and Director of Clinical Research at Massachusetts General Hospital Cancer Center, and clinical advisor to Scancell commented:

*"Although checkpoint inhibitor combinations have improved outcomes for patients with melanoma, the toxicity of combinations such as ipilimumab plus nivolumab means that there remains a need to develop combinations with other investigational agents such as SCIB1, which have the potential to improve response rates without increasing toxicity."*

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

*"We are delighted that our IND is now open, allowing us to progress our SCIB1 Phase 2 trial in the US as well as the UK. Approval will allow us to increase our overall patient recruitment rate and determine whether the addition of SCIB1 to current, standard of care treatment with pembrolizumab increases the anti-cancer response rate in patients with metastatic melanoma."*

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

### **For Further Information:**

**Scancell Holdings plc**

Dr John Chiplin, Chairman

Dr Cliff Holloway, CEO

+44 (0) 20 3727 1000

**Panmure Gordon (UK) Limited**

**(Nominated Adviser and Corporate broker)**

Freddy Crossley/Emma Earl

+44 (0) 20 7886 2500

**FTI Consulting**

Simon Conway/Natalie Garland-Collins

+44 (0) 20 3727 1000

### **About Scancell**

Scancell is developing novel immunotherapies for the treatment of cancer based on its ImmunoBody®, Moditope® and AvidiMab™ 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.

AvidiMab™ is a patent protected technology platform which increases the avidity of human antibodies by promoting non-covalent Fc-Fc interactions. This modification induces the direct tumour cell killing properties of Scancell's anti-glycan monoclonal antibodies (mAbs) but has broad potential to increase the avidity or potency of any therapeutic monoclonal antibody including those being developed for autoimmune diseases, as well as cancer.

For further details, please see our website: [www.scancell.co.uk](http://www.scancell.co.uk)