

25 April 2019

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

Scancell announces UK regulatory approval to start SCIB1 Phase 2 trial in patients with advanced melanoma

Dosing in UK arm due to commence during this quarter, as planned

Scancell Holdings plc, the developer of novel immunotherapies for the treatment of cancer, is pleased to announce that it has received all of the UK regulatory, ethical and legal approvals required to initiate the Phase 2 clinical trial to assess the safety and efficacy of SCIB1 in metastatic melanoma patients also receiving the checkpoint inhibitor pembrolizumab (Keytruda). The UK arm of the study is therefore expected to start during the second quarter of this year, as planned.

SCIB1 has completed a Phase 1/2 clinical trial in patients with Stage III/IV malignant melanoma. In this study SCIB1 was shown to have a favourable safety profile with no dose-limiting toxicities and no serious adverse events related to study drug or delivery device. Survival with SCIB1 treatment appears superior to historical survival rates, with 14 of 16 resected patients receiving 2-4 mg doses surviving for more than five years (as reported in February 2018).

Although pembrolizumab is an approved checkpoint inhibitor therapy for advanced melanoma, response to treatment is limited to only a subset of patients (circa 30%). The Phase 2 study is therefore designed to assess whether the addition of SCIB1 treatment 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. SCIB1 will be administered using Ichor's TriGrid® v2.0 electroporation delivery system.

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

"This is a major milestone in the clinical advancement of our SCIB1 programme and we look forward to initiating this important Phase 2 study. Our preclinical research has indicated that SCIB1 administration with an immune checkpoint inhibitor has the potential to offer even greater efficacy than when either agent is given alone and this new study is designed to evaluate the safety and efficacy of this approach in patients with inoperable disease.

Discussions with the FDA are on-going and we continue to work with Ichor towards IND approval to open our US study centres."

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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 can be used as monotherapy or in combination with checkpoint inhibitors. 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 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