Scancell

FDA clears global Phase III trial for iSCIB1+

26 January 2026

- Scancell has received FDA clearance for the registrational Phase III trial of iSCIB1+ in advanced melanoma, a major milestone for the company. Details of the study design have not yet been disclosed, but it is likely to be a multinational, multi-centre, blinded study (with key centres in the US, UK, and Europe) enrolling c 450-500 patients and, given regulator preference for survival endpoints as a more robust measure of patient benefit, we expect the primary efficacy endpoint will be progression free survival (PFS). We previously noted (November 2025 Outlook) that a pre-specified interim data read-out would be typical in a registrational oncology trial and, if included, this could potentially be used to seek accelerated approvals while the trial runs to completion. FDA approval of the proposed trial makes discussions with other regulators, namely MHRA in UK and EMA in Europe, easier.
- The IND application was supported by the strong data from the open label Phase II SCOPE trial in advanced melanoma, in which Cohort 1 (SCIB1) and Cohort 3 (iSCIB1+) evaluated the addition of SCIB1/iSCIB1+ to double checkpoint inhibitors (CPIs) nivolumab and ipilimumab, now considered SoC (standard of care). These promising results (July 2025 Lighthouse) prompted selection of iSCIB1+, which is active in 80% of melanoma patients whereas SCIB1 is active in 30%-40% of patients. PFS is a key study metric: in the target HLA population (n=39) of Cohort 3 PFS was 74% at 16 months. Reported PFS for doublet therapy alone is 50% at 11.5 months (CheckMate-067 data), which, for context, were the highest observed in such advanced melanomas. Importantly, the favourable PFS is consistent across subgroups including PD-L1 status, BRAF status, and prior checkpoint inhibitor exposure.
- The approval on the design of the registrational trial for iSCIB1+ clears a major hurdle, confirming agreement on wider factors such as dose, manufacturing, and the existing clinical package addressing safety and efficacy. With a clear pathway for iSCIB1+'s further clinical development, management focus can now shift firmly to evaluating the financing options, with active discussions with potential partners known to be underway.

Trinity Delta view: Scancell's investment case centres on the potential of the lead oncology programmes from its highly promising ImmunoBody and Moditope "off the shelf" platforms. iSCIB1+ already forms the majority of our current rNPV (51.3%) and this is set to rise as Scancell navigates key de-risking events such as securing the funding for iSCIB1+ to enter this pivotal Phase III study. The quality and duration of responses seen in SCOPE provide reassurance that iSCIB1+ could alter standard of care in advanced melanoma if replicated in the registrational trial. Investor attention will now focus on the likely funding mechanism for the trial, with partnership expected to be one of the principal avenues under consideration. Our rNPV valuation is £382m, or 37p/share, with further upside potential as iSCIB1+ progresses and the expected news flow from both the Moditope platform (Phase I/II ModiFY data from the renal cell carcinoma cohort exploring Modi-1 with doublet CPIs) and the GlyMab portfolio.

Price	13.20p
Market Cap	£137.0m
Primary exchange	AIM
Sector	Healthcare
Company Code	SCLP
Corporate client	Yes

Company description:

Scancell is a clinical-stage immuno-oncology specialist. The key value drivers are iSCIB1+, the lead ImmunoBody programme, and Modi-1, the lead Moditope programme. The novel GlyMab glycan antibodies are earlier in development.

Analysts

Lala Gregorek
lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori
fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Lala Gregorek lgregorek@trinitydelta.org
+44 (0) 20 3637 5043

Franc Gregori fgregori@trinitydelta.org
+44 (0) 20 3637 5041

Disclaimer

More information is available on our website: www.trinitydelta.org