SCANCELL

SCANCELL HOLDINGS PLC

Scope 2 melanoma trial beats milestones

Abstract

Scancell's Phase 2 SCOPE trial for advanced melanoma impressed – with Initial data from 11 patients showing an 82% objective response rate (ORR) to treatment, handily surpassing the 50% ORR seen with competing drugs.

SCIENTIFIC AND BUSINESS UPDATE

We are excited by Scancell's SCOPE 2 melanoma trial results: Scancell is a core investment for Vulpes – we hold almost 15% of the company and have always been very impressed with the science. It has years of solid research in 2 main areas: a) cancer vaccines – produced across the Moditope® and ImmunoBody® platforms, and b) antibody products – produced across the GlyMab™ and AvidiMab® platforms. Scancell's platforms target over 10 types of solid tumours ; it is thus a de-risked business model, with multiple shots on goal, unlike peers that might be narrowly focused on only 1 or 2 therapeutic indications. We think these test results will make big pharma take notice, given the highly lucrative immuno-oncology industry. For more details, refer to our detailed report on Scancell at this link - *Scancell Holdings Plc: Multiple Arrows in its Quiver*. (ctrl + click to follow the link).

Scancell has shown startling results in its SCOPE trial: Over 80% of the malignant melanoma patients responded and the trial ended prematurely since the endpoint had already been reached. At 13 weeks, the reduction in tumour volume was 31%-94%. Four patients reached the 25 weeks imaging evaluation and two reached the 37 weeks evaluation and have shown a 69%-94% and 87%-94% reduction in total tumour burden, respectively. This compares to an ORR (objective response rate) of 50% reported in patients just receiving this doublet CPI therapy in the real world setting. This is a major achievement that not only bodes well for melanoma patients, but it also vindicates the DNA vaccination approach. The phase II study SCOPE was run using a combination of the SCIB1 DNA vaccine together with two CPIs, Ipilimumab plus Nivolumab.

What is melanoma: Melanoma is a type of skin cancer that is very aggressive. It affects over 3 million people a year and is very common in Australia and New Zealand. Early detection combined with surgery is the most effective treatment as it becomes much more difficult to treat later.

Traditional vaccine-based approaches to cancer have had limited success: With a low response rate of 5-7%. The reason is the area around the tumour is highly immunosuppressive. Notably, Scancell ran an earlier Phase 1/2 clinical trial of its DNA vaccine SCIB1 alone, with 14 out of 16 stage 4 patients (89%) surviving for more than the 5 years following vaccination. This 89% survival rate is significantly better than 5 year survival rate of 52% seen in the nivolumab+ ipilimumab doublet treatment, as also the 44% / 26% survival rates respectively in the stand-alone nivolumab or ipilimumab treatments.

More about SCIB1: SCIB1 is a circular DNA that encodes an antibody in the base of which is a sequence that binds strongly to antigen presenting immune cells ensuring efficient uptake. At the other end of the antibody, the business end that captures foreign proteins, they have engineered in 3 binding sites for 3 proteins that are produced by melanoma cells. This ensures that they can target most of the cancers cells which being highly heterogeneous may not present all of the proteins but at least one will be there to allow binding and stimulation of the killer cells to destroy the cancer cells. Given three different targets it will be difficult for the cancer cells to develop resistance. The administration of SCIB1 has shown no adverse effects that have been seen in other immunotherapy regimes. That has been completed.

SCIB1's other major advantages: being circular DNA it is extremely stable in the body and can be produced very rapidly in bulk. It is stable as a powder at room temperature and requires no temperature-controlled environment for shipment or storage. It can be easily administered intramuscularly to the patient using a needle-free injection system. Smooth muscle cells are very long lived compared to most other cells in the body, living for up to 16 years. This ensures that the antibody production is almost continuous and will suppress recurrence over a long period.

Sizing the malignant melanoma market opportunity: We estimate the malignant melanoma market opportunity in 10 key markets (Australia, US, UK, key western Europe markets, India and China) to be at around 280,000 patients per annum, which drops to around 200,000 patients are adjusting for diagnosis treatment and compliance rates. Utilising prudent assumptions, we estimate the market size to be around US$3bn per annum.

Valuation implications for Scancell: Assuming no price inflation, an r factor of 30% and a peak market share of 50%, we reckon that the rNPV of this drug is – at present – around US$30m to US$220m. This assumes a scenario of 3 royalty rates of 5%, 10% and 15%. At the mid-point of 10%, the rNPV of US$125m is three – fourths Scancell's current market capitalization. We continue to view the current share price as derisory; reflective of poor market sentiment for biotech stocks and the early-stage nature of the business, with management too focused on the science, rather than medium- and long-term commercial aspects.

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