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Sareum Holdings

Regulatory update

Sotyktu approval positive read-across for SDC-1801

Pharma and biotech

On 9 September 2022 the US FDA approved Bristol Myers Squibb's (BMS) first-in-class tyrosine kinase 2 (TYK2) inhibitor Sotyktu (deucravacitinib) for the treatment of moderate-to-severe plaque psoriasis in adults, making it the first selective TYK2 inhibitor to be approved for any indication. We expect this news to have a positive read-across for Sareum Holdings' lead asset, SDC-1801, a dual TYK2/JAK 1 inhibitor. As a reminder, Sareum recently announced the filing of a clinical trial authorisation application for SDC-1801 with the UK Medicines and Healthcare products Regulatory Agency. The Phase 1a (in healthy subjects) is planned to commence in Q4 CY22, and a Phase 1b (in psoriasis patients) is planned to commence in CY23 subject to regulatory approval. The approval of Sotyktu was widely expected and validates the potential of this new asset class, in our opinion. Sareum asserts that SDC-1801's dual targeting could potentially accord superior efficacy, which if proved could translate to a sizeable market opportunity for Sareum.

Year end	Revenue (£m)	PBT (£m)	EPS (p)	DPS (p)	P/E (x)	Yield (%)
06/18	0.0	(1.5)	(0.06)	0.0	N/A	N/A
06/19	0.0	(1.5)	(0.05)	0.0	N/A	N/A
06/20	0.04	(1.0)	(0.03)	0.0	N/A	N/A
06/21	0.0	(1.5)	(0.05)	0.0	N/A	N/A

Source: Company data

Sotyktu's approval was based on the results from the Phase III POETYK PSO-1 and POETYK PSO-2 trials, which evaluated the safety and efficacy of a 6mg/day dose of Sotyktu with placebo and the current mainstay, Otezla (30mg twice daily). POETYK PSO-1 enrolled 664 patients, while POETYK PSO-2 included 1,020 patients. The co-primary endpoints were the percentage of patients achieving PASI 75 (or a 75% skin clearance on the psoriasis area and severity index) and the percentage of patients achieving a static Physician's Global Assessment score of 0 or 1 at week 16. At week 16, 58.7% and 53.6% of patients on Sotyktu achieved a PASI 75 response versus the respective 12.7% and 9.4% receiving placebo and 35.1% and 40.2% of patients on Otezla across both trials. More importantly, the drug showed no material toxicology issues, which has been a particular concern regarding the JAK class of drugs recently, resulting in black box warnings.

Around 2–3% of the global population is believed to be suffering from psoriasis with an estimated eight million patients in the United States alone. The global psoriasis market was valued at US$24.3bn in 2021 and is estimated to reach US$47.2bn by 2029, highlighting the significant market potential.

Sotyktu's FDA approval was widely expected following data readouts from the two head-to-head clinical trials and validates the potential for the TYK2 class. We note that Sotyktu's mechanism of action (allosteric approach) is different from SDC-1801's traditional ATP approach although the latter's dual selectivity could result in broader inhibition and potentially superior efficacy to Sotyktu. SDC-1801's Phase Ia trial is expected to commence in Q4 CY22.

13 September 2022

Price	**160p**
Market cap	**£109m**
Net cash (£m) at 30 June 2022	4.3
Shares in issue	68.07m
Free float	94.9%
Code	SAR
Primary exchange	AIM
Secondary exchange	N/A

Share price performance

Business description

Sareum Holdings is a UK-based drug development company, specialising in small molecule kinase inhibitors. Its lead programmes are its preclinical TYK2/JAK1 inhibitors, SDC-1801 for autoimmune diseases and SDC-1802 for cancer. SDC-1801 filed a CTA application in July 2022, with Phase Ia trial expected in Q4 CY22. Other programmes include the CHK1 inhibitor SRA737, out-licensed to Sierra Oncology (acquired by GSK in 2022) and the de-prioritised FLT3+Aurora kinase. Sareum holds a 27.5% stake in the economics of the SRA737 licence agreement.

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