Sareum Holdings

A decisive step towards Phase II

Sareum Holdings has reported the initiation of toxicology studies required ahead of the Phase II studies for its lead TYK2/JAK1 asset, SDC-1801. We view this as a key milestone in SDC-1801's development plan, with results likely to bolster any upcoming discussions with potential licensing partners. The studies will evaluate SDC-1801's general toxicology and potential drug-drug interactions, with completion expected in Q4 CY25. With a cash runway into 2026, the company is well funded to reach this milestone. This news follows Sareum's recent decision to test its TYK2/JAK1 programme in central nervous system (CNS) indications, following supportive preclinical data. TYK2/JAK1 mediate the activity of neuroinflammatory cytokines, such as IL-6, IL-12, IL-23, IFN-α/β, and are emerging as potential targets in CNS, a space that has seen a resurgence in activity and investor interest.

The commencement of toxicology studies marks an important step in SDC-1801's planned progression towards Phase II clinical studies. The toxicology studies, expected to last up to 16 weeks plus a recovery period, are a key regulatory requirement prior to the initiation of longer-term Phase II studies, with psoriasis expected to be the initial focus. Alongside the toxicology studies (which are being conducted by a contract research organisation), Sareum has been focusing on optimising the formulation and drug substance re-synthesis to align with Phase II requirements. We expect data from the toxicology studies to support management's discussion with prospective licensing partners for SDC-1801.

This development follows Sareum's announcement to evaluate its TYK2/JAK1 programme in CNS indications. Management highlighted that it has tested a total of six compounds from its proprietary Sareum Kinase Inhibitor Library in preclinical studies, assessing their ability to cross the blood-brain barrier (a key consideration from any drug being developed for neurological indications), with encouraging initial results. The company will work on optimising the compounds before deciding on the next steps for preclinical development.

The CNS space has witnessed increasing traction in recent months and TYK2/JAK1's potential in neuroinflammatory conditions is a key area of interest. The asset class already has some early validation in CNS from Biohaven's brain-penetrant TYK2/JAK1 inhibitor, BHV-8000, which recently commenced a Phase II/III trial in Parkinson's disease. Notably, Biohaven acquired the rights for BHV-8000 (TLL-041) from TLL Pharmaceutical in March 2023 (at Phase I-ready stage). The transaction included an upfront payment of $20m and up to $950m in milestone payments, highlighting the significant potential of early-stage assets in this category.

Historical financials

Year end	Revenue (£m)	PBT (£m)	EPS (p)	P/E (x)
6/21	0.0	(1.7)	(2.30)	N/A
6/22	0.0	(2.6)	(3.20)	N/A
6/23	0.0	(4.0)	(4.70)	N/A
6/24	0.0	(4.6)	(4.20)	N/A

Source: Company data

Healthcare

3 June 2025

Price	**14.25p**
Market cap	**£19m**

Share price performance

Share details

Code	SAR
Listing	AIM
Shares in issue	134.4m
Net cash/(debt) at 31 December 2024	£4.1m

Business description

Sareum Holdings is a UK-based drug development company, specialising in small molecule kinase inhibitors. Its lead programmes are TYK2/JAK1 inhibitors, SDC-1801 for autoimmune diseases and SDC-1802 for cancer. Lead asset SDC-1801 reported positive Phase I data in June 2024, with Phase II readiness expected by Q4 CY25. Other programmes include the CHK1 inhibitor SRA737, for which Sareum acquired the licence in March 2025, corresponding to a 63.5% economic interest versus 27.5% held previously.

Bull points

- SDC-1801's dual TYK2/JAK1 selectivity may provide a competitive edge to peers, pending clinical validation of efficacy.
- First-in-class opportunity for SDC-1802 and SRA737 in multiple cancer indications.
- Approval of Sotyktu provides regulatory feasibility for TYK2 inhibitors.

Bear points

- Potential funding challenges due to possible partnering delays affecting clinical progress of SDC-1801 and SDC-1802.
- Safety/efficacy profile of TYK2/JAK1 inhibitors needs to be proved in larger randomised trials.
- Markets sought by SDC-1801 and SDC-1802 are highly competitive.

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