

Sareum Holdings PLC

("Sareum" or the "Company")

Sareum announces approval to initiate Phase 1 clinical trial of its lead product SDC-1801

Cambridge, UK, 5 May 2023- Sareum Holdings plc (AIM: SAR), a biotechnology company developing next generation kinase inhibitors for autoimmune disease and cancer, is pleased to announce that its application to conduct Phase 1 clinical studies on SDC-1801 in Australia has been granted approval.

SDC-1801 is a TYK2/JAK1 inhibitor being developed as a potential new therapeutic for a range of autoimmune diseases with an initial focus on psoriasis, an autoimmune condition affecting the skin. The Company's application under the Clinical Trial Notification (CTN) scheme has been approved by the Human Research Ethics Committee (HREC) and acknowledged by Australia's medicines regulator, the Therapeutic Goods Administration (TGA), meaning the Phase 1 trial is now able to proceed.

With the approval, Sareum, working alongside specialist clinical units in Melbourne, Australia, expects to initiate a Phase 1a trial as soon as possible to investigate the safety and pharmacokinetics of an oral formulation of SDC-1801 in ascending doses administered to healthy subjects.

Provided satisfactory safety data are obtained from this initial study, a Phase 1b clinical study is expected to commence in psoriasis patients in 2024.

Further details of the clinical trial are available on the Australian New Zealand Clinical Trials Registry website at <https://www.anzctr.org.au/TrialSearch.aspx#&&searchTxt=SDC-1801>.

TYK2/JAK1 inhibition has demonstrated benefits in maintaining a healthy immune system and has strong clinical validation in psoriasis and psoriatic arthritis. Psoriasis is an autoimmune dermatological condition affecting more than 60 million adults worldwide, with a market size for potential treatments estimated to be worth more than US\$30 billion. Sareum believes that TYK2/JAK1 inhibition offers potential for increased efficacy in psoriasis, compared with existing approved therapies.

Dr Tim Mitchell, CEO of Sareum, commented:

"The approval of this application is a very important step for Sareum and we are now ready to bring our lead asset into clinical development. We are very excited about the potential of SDC-1801, which we believe could offer superior efficacy compared to other currently-available small molecules for psoriasis and which has demonstrated a good safety profile in preclinical studies. We look forward to initiating our Phase 1 trial in the coming weeks."

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The information contained within this announcement is deemed to constitute inside information as stipulated under the Market Abuse Regulations (EU) No. 596/2014, which is part of UK law by virtue of the European Union (Withdrawal) Act 2018.

About Sareum

Sareum Holdings (AIM:SAR) is a biotechnology company developing next generation kinase inhibitors for autoimmune disease and cancer.

The Company is focused on developing next generation small molecules which modify the activity of the JAK kinase family and have best-in-class potential. Its lead candidate, SDC-1801, simultaneously inhibits TYK2 and JAK1. SDC-1801 is a potential treatment for a range of autoimmune diseases, which is planned to enter clinical development with an initial focus on psoriasis.

Sareum has an economic interest in SRA737, a clinical-stage Chk1 inhibitor which it originally developed in collaboration with several Cancer Research UK-related organisations. SRA737 has shown promising safety and efficacy in two Phase 1/2 clinical trials.

Sareum is also developing SDC-1802, a TYK2/JAK1 inhibitor with a potential application for cancer immunotherapy.

Sareum Holdings plc is based in Cambridge, UK, and is listed on the AIM market of the London Stock Exchange, trading under the ticker SAR. For further information, please visit the Company's website at www.sareum.com

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