

Update on Progress of SAKK Investigator-Initiated Phase 1b trial of Docetaxel Micellar in Advanced Prostate Cancer

Solna, Sweden 23 February 2022 – Oasmia Pharmaceutical AB (Oasmia), an oncology-focused specialty pharmaceutical company, today announces that the first patient has now fully completed the study in the Investigator-Initiated Phase 1b trial of Docetaxel micellar for advanced prostate cancer (trial SAKK 67/20 of the Swiss Group for Clinical Cancer Research SAKK). Furthermore, the first of three dosing groups in the trial has been successfully recruited and the first patient has started in the second dose group.

Francois Martelet, MD, Chief Oasmia Officer, Oasmia, commented: “We are grateful for the significant effort of the Swiss Group for Clinical Cancer Research (SAKK), our investigators and clinics have made in progressing the study so far. SAKK has informed us that it is well-positioned to complete recruitment this year and secure data crucial for the continued development of Docetaxel micellar.”

Oasmia's Docetaxel micellar is a solvent-free formulation of docetaxel developed to avoid the need for the solubility enhancers in solvent-based docetaxel, and the mandatory high-dose steroid premedication, while providing an effective treatment option. Prostate cancer is a significant and increasingly prevalent health problem worldwide and is the leading cause of male cancer deaths.

The SAKK 67/20 trial ([NCT04629781](https://clinicaltrials.gov/ct2/show/study/NCT04629781)) is an open-label, multicenter, single-stage Phase 1b trial at major hospitals in Switzerland, recruiting 18 chemotherapy-naïve patients with metastatic castration resistant prostate cancer (mCRPC) with adequate bone marrow, liver, and renal function. The primary objective of this trial is to determine the maximum tolerated dose of Docetaxel micellar in patients with mCRPC and the secondary objectives are to evaluate safety, assess the preliminary anti-tumor activity, and to characterize the pharmacokinetics in this population.

For More Information:

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About Oasmia Pharmaceutical AB

Oasmia is a specialty pharmaceutical company focused on the development of new therapeutic options for patients suffering from hard-to-treat cancers. It has a growing pipeline of clinical-stage assets targeting late-stage cancers. Apealea® (paclitaxel micellar) is being made available to

ovarian cancer patients through a partnership with Elevar Therapeutics, Inc. Development programs include Cantrixil, in clinical development for late-stage ovarian cancer, and docetaxel micellar, in development for advanced prostate cancer. Oasmia has proprietary drug delivery technology designed to improve solubility, efficacy and safety. Oasmia's shares are traded on Nasdaq Stockholm (OASM). To find out more about Oasmia please visit www.oasmia.com.

About SAKK

The Swiss Group for Clinical Cancer Research (SAKK) is a non-profit organization, which has been conducting clinical trials in oncology since 1965. Its primary objective is to research new cancer therapies, to develop existing treatments further and to improve the chances of a cure for patients with cancer. This takes place through cooperative projects within Switzerland and in collaboration with centers and study groups abroad. SAKK is supported by a service-level agreement with the Swiss State Secretariat for Education, Research and Innovation (SERI) and also by partners such as the Swiss Cancer League and Swiss Cancer Research. For more information, please visit www.sakk.ch.

Attachments

[Update on Progress of SAKK Investigator-Initiated Phase 1b trial of Docetaxel Micellar in Advanced Prostate Cancer](#)