

## First Patient enrolled in the SAKK Investigator-Initiated Phase 1b trial of Docetaxel Micellar in Advanced Prostate Cancer

Stockholm, Sweden, 10 June 2021 – Oasmia Pharmaceutical AB, an innovation-focused specialty pharmaceutical company, today announces that the first patient has been dosed in a Phase 1b clinical trial of Oasmia's Docetaxel micellar in patients with advanced prostate cancer. The trial is being conducted by the Swiss Group for Clinical Cancer Research (SAKK).

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.

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. For more information, please visit [www.sakk.ch](http://www.sakk.ch).

### **Professor Markus Jörger, President Project Group Developmental Therapeutics at**

**SAKK commented:** "It is a significant step to have dosed the first patient in this Phase 1b trial of Docetaxel micellar in advanced prostate cancer patients. Docetaxel micellar has the potential to remove the need for pretreatment with corticosteroids, thereby not adding more steroid to patients who have had significant prior steroid administration leading to marked bone fragility, exacerbated by cancer metastases in the bone, or may have steroid-related metabolic issues."

**Heidi B. Ramstad, M.D., Chief Medical Officer of Oasmia, commented:** "We are pleased to be partnering with SAKK on this trial which we believe is an important step towards evaluating whether Docetaxel micellar can be a treatment option for patients with advanced prostate cancer, without the mandatory steroid use that is necessary with existing, solvent-based docetaxel formulations."

### **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. Oasmia's most advanced program is Apealea® (paclitaxel micellar), which is being made available to ovarian cancer patients through a partnership with Elevar Therapeutics, Inc. Other development programs include Cantrixil, in clinical development for late-stage ovarian cancer, and docetaxel micellar, in development for advanced prostate cancer. Oasmia's proprietary drug delivery platform XR-17™ is designed to improve drug solubility, efficacy and safety. Oasmia's shares are traded on Nasdaq Stockholm (OASM). To find out more about Oasmia please visit [www.oasmia.com](http://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 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](http://www.sakk.ch).

### **Attachments**

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