

## Vivesto announces early termination of patient enrollment in the investigator-initiated Phase 1b Docetaxel micellar study

Solna, August 4, 2023 - Vivesto AB, an oncology-focused research and development company, today announced early termination of patient enrollment in the Docetaxel micellar advanced prostate cancer Phase 1b study with the Swiss Group for Clinical Cancer Research (SAKK).

The open-label, multicenter, single-stage Phase 1b study has closed its accrual after enrollment of 11 of the planned 18 patients, since Vivesto believes that the data generated will be sufficient ahead of switching into development with a new formulation based on its improved XR-18 micelle technology platform.

Docetaxel micellar has shown good tolerability at doses considered standard for conventional docetaxel formulations, as well as signs of clinical activity. Docetaxel micellar has been well received by investigators of the SAKK 67/20 and by participating prostate cancer patients.

"We are grateful for the general positive feedback from the principal investigators. Particularly, Docetaxel micellar was safely administered with no infusion reactions and without the requirement for steroid premedication. A thorough analysis of the data, including pharmacological aspects, is pending, and we will await its completion to gain a comprehensive understanding of the outcomes," said Heidi Ramstad, Vivesto's CMO. "We are grateful to the enrolled patients and for the effort put in by SAKK and investigators in search for better treatment options for prostate cancer."

Vivesto's Docetaxel micellar is a solvent-free formulation of docetaxel developed to avoid the need for the solubility enhancers in a solvent-based docetaxel and the mandatory high-dose steroid premedication. Patients treated with other existing formulations of docetaxel require steroid administration to avoid certain serious adverse events related to the formulations with solvent. The administration of steroids can lead to marked bone fragility, exacerbated by cancer metastases in the bone, or steroid-related metabolic issues.

Vivesto has progressed in the development of its XR-18 drug delivery platform and intends to use this next-generation improved technology in future development of Docetaxel micellar.

### For More Information:

Erik Kinnman, Chief Executive Officer at Vivesto

Phone: +46 018-50 54 40

E-mail: [IR@vivesto.com](mailto:IR@vivesto.com)

### About Vivesto AB

Vivesto is a research and development company that develops new treatment options for patients suffering from difficult-to-treat cancer. The company has a portfolio of projects with the potential of offering cancer patients with unmet medical needs new treatment alternatives. Vivesto has a track-record of developing drugs from the preclinical stage, through clinical development to regulatory approval. Vivesto's most advanced program Apealed® (paclitaxel micellar) has been granted

market approval in the EU as a treatment for adult patients suffering from the first relapse of platinum sensitive epithelial ovarian cancer, or primary peritoneal cancer or fallopian tube cancer. Other clinical development programs include Cantrixil for late-stage ovarian cancer, and Docetaxel micellar, in development for advanced prostate cancer. Moreover, the company is developing Paccal Vet (paclitaxel micellar) for malignant melanoma and hemangiosarcoma in dogs. Vivesto has developed proprietary drug delivery technologies designed to improve solubility of various active pharmaceutical ingredients.

Vivesto's shares are traded on Nasdaq Stockholm (ticker: VIVE). Visit [www.vivesto.com](http://www.vivesto.com) for more information about Vivesto.

#### **About the SAKK 67/20 trial**

The SAKK 67/20 trial ([NCT04629781](https://clinicaltrials.gov/ct2/show/study/NCT04629781)) is an open-label, multicenter, single-stage Phase 1b trial conducted at major hospitals in Switzerland, aimed at investigating the efficacy of Docetaxel micellar in the treatment of chemotherapy-naïve patients with metastatic castration resistant prostate cancer (mCRPC) with adequate bone marrow, liver and renal function.

#### **About the Swiss Group for Clinical Cancer Research**

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).

#### **Attachments**

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