Phase 1b Trial of Oasmia's Docetaxel Micellar in Advanced Prostate Cancer is Granted Ethical Committee Approval and can be Initiated

Oasmia's docetaxel micellar formulation is designed to improve the solubility of docetaxel without solubility enhancers and avoid the mandatory use of steroid pre-medication

Uppsala, Sweden, 21 April 2021 – Oasmia Pharmaceutical AB, an innovation-focused specialty pharmaceutical company, is pleased to announce that Swissmedic and Swissethics approval has been received to initiate a Phase 1b clinical trial with the Swiss Group for Clinical Cancer Research (SAKK) of Oasmia's Docetaxel micellar in patients with advanced prostate cancer. Trial initiation is expected to commence in the first half of 2021.

Bone metastases in advanced prostate cancer are common and cause bone fragility. During the long course of the disease, corticosteroids are used, and corticosteroid premedication is mandatory with solvent-based docetaxel. High-dose steroid use is known to change the bone metabolism and further increase the fragility risk in these patients. Bone fractures impact patients' quality of life and may also reduce survival time.

Oasmia's Docetaxel micellar is a solvent-free formulation of docetaxel to avoid the need for solubility enhancers and mandatory high-dose steroid premedication while providing an effective treatment option. Docetaxel is approved for a wide range of solid malignancies and is a standard of care for advanced prostate cancer.

The SAKK 67/20 trial (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. Using a standard Phase I trial design, the primary objective of this study is to determine the maximum tolerated dose of Docetaxel micellar in patients with mCRPC. The secondary objectives are to evaluate the safety of Docetaxel micellar, to assess the preliminary anti-tumor activity, and to characterize the pharmacokinetics of Docetaxel micellar in this population. The treatment will be a 21-day cycle of one of three dose levels of Docetaxel micellar until progression or occurrence of unacceptable toxicity or withdrawal, for a maximum of 10 cycles.

Prostate cancer is a significant and increasingly prevalent health problem worldwide and is the leading cause of male cancer deaths.

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.

Professor Markus Jörger, President Project Group Developmental Therapeutics, at SAKK commented: "We approached Oasmia about collaborating on a clinical trial in advanced prostate cancer using Docetaxel micellar as we saw the potential to remove pre-treatment with corticosteroids, thereby greatly reducing the incidence of adverse events such as bone fractures and other skeletal related events. We are optimistic that Docetaxel micellar could provide a much-needed treatment option for patients with advanced prostate cancer."

Commenting on the clinical trial approval, Heidi B. Ramstad, M.D., Chief Medical Officer of Oasmia, said: "SAKK approached us to collaborate on this clinical trial and we are delighted to be partnering with such a prestigious organization in oncology with a distinguished history in clinical trials. We believe that Docetaxel micellar could provide a new treatment option for patients with advanced prostate cancer, without the mandatory steroid use that is necessary with existing, solvent-based docetaxel formulations."

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About Oasmia Pharmaceutical AB
Oasmia is a specialty pharma company dedicated to improving the lives of patients by enhancing the intravenous delivery of established and novel drugs in significant diseases, including cancer. Product development is based on Oasmia's proprietary drug delivery platforms which can be applied to medicines used in many therapeutic areas, to develop water soluble formulations of drugs that currently require chemical solubilizers for dissolution. The first product approved using this technology is Apealea® (paclitaxel micellar). Apealea has received market authorization in the European Union and several other territories for the treatment of first relapse in platinum-sensitive ovarian cancer, in combination with carboplatin. The Company is making Apealea accessible to patients through its partnership with Elevar Therapeutics, together with its existing commercial operations in the Nordic region. Oasmia's shares are traded on the Nasdaq Stockholm stock exchange (ticker: 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. The 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, info@sakk.ch.

Attachments

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