

Oasmia Pharmaceutical AB Signs Phase 1b Trial Agreement with SAKK, The Swiss Group for Clinical Cancer Research for Evaluation of Docetaxel Micellar

Uppsala, Sweden, June 8, 2020 – Oasmia Pharmaceutical AB has partnered with the Swiss Group for Clinical Cancer Research (SAKK) to conduct the first clinical trial of Oasmia’s docetaxel micellar compound in advanced prostate cancer. Prostate cancer in men is a significant health problem worldwide and is a leading cause of cancer death in men. Oasmia’s docetaxel micellar formulation uses Oasmia’s proprietary solubility technology platform enabling the intravenous administration of water-insoluble compounds without traditional solubility enhancers. Oasmia’s solubility technology platform has been utilized in another product, Apealea®, which has obtained Marketing Authorization in the EU in 2018, in combination with carboplatin for the treatment of adult patients with first relapse of platinum-sensitive ovarian cancer.

Docetaxel (INN) is a widely approved anticancer drug with proven activity against a wide range of solid malignancies and represents a standard of care option for advanced prostate cancer. The new Oasmia formulation of docetaxel, to be investigated in this clinical trial, docetaxel micellar, is intended to improve the solubility of docetaxel and avoid the mandatory use of steroid pre-medication.

The Executive Board of SAKK was unanimous in making the decision to carry out the clinical trial. In view of the urgent need for new treatment options in this disease stage, affecting many men all over the world, several Swiss qualified hospital centres have confirmed their participation in this initial study in patients suffering from advanced prostate cancer.

Pursuant to the collaboration agreement, SAKK is the legal sponsor of the project and responsible to conduct the phase 1B trial in accordance with the protocol and applicable rules and regulations. Oasmia’s main role in the project is to supply its formulation of docetaxel and carry the cost of the trial, which are deemed not material to Oasmia.

Prof.Dr. med. Markus Jörger MD-PhD, President of the SAKK Project Group “Developmental Therapeutics”, commented on the trial: *“The investigational drug docetaxel micellar may be a promising alternative to solvent-based docetaxel formulations in advanced prostate cancer, to avoid mandatory use of steroid premedication”.*

Francois Martelet, M.D., CEO of Oasmia, comments: *“We are pleased to enter into this agreement. It provides an cost-efficient opportunity to test our formulation in collaboration with SAKK, an organization with extensive clinical trial experience, and take us further in our goal to develop new drugs based on our proprietary technology platform XR17.”*

About Oasmia Pharmaceutical

Oasmia Pharmaceutical AB develops, manufactures, markets and sells an improved generation of drugs within human and veterinary oncology. Oasmia produces novel formulations of well-established cytostatic agents which show improved performance, an improved side-effect profile and a wider range of therapeutic areas compared with existing alternatives. Product development is based on Oasmia's proprietary technology platform XR17. Oasmia has been successful in moving its first product candidate, Apealea® (paclitaxel micellar), through clinical development, and has received market authorization in the European Union and other territories.

About Swiss Group for Clinical Cancer Research (SAKK)

SAKK is a committed non-profit organization for clinical cancer research, and aims to explore new cancer therapies, improving existing treatments and to improve the prognosis of cancer patients. This is done through cooperation within Switzerland and in cooperation with foreign centres and study groups. The regular members of SAKK, the main clinical oncology centres at the cantonal and regional hospitals and university hospitals are organized together into an association. Since 1965, SAKK has been an independent Institution for multicentre clinical trials of phases I, II and III through the major Swiss hospitals. Due to their network and experience, SAKK is a strong partner to carry out a clinical trial. <https://www.sakk.ch/en>

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Attachments

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