

Vivesto announces Inceptua decision to withdraw market authorization application for Apealea® in Switzerland

Solna, Sweden, January 11, 2023 – Vivesto AB, an oncology-focused specialty pharmaceutical company, announced today that Inceptua AB (a partner and sublicensee of Elevar Therapeutics Inc.), which holds the right to commercialize Apealea® (paclitaxel micellar) in the European Union, UK and Switzerland, has decided that the market authorization application for Apealea, submitted to the Swiss Agency for Therapeutic Products (Swissmedic) on 15 November 2021, will be withdrawn.

Swissmedic has concluded that based on current clinical data, a positive benefit-risk balance has not been proven for Apealea and has therefore indicated refusal of marketing authorization. There are currently no plans for further clinical development to accommodate approval in Switzerland for commercial reasons.

Apealea in combination with carboplatin is indicated for the treatment of adult patients with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer. The product is approved by the European Medicines Agency (EMA) and the Medicines & Healthcare products Regulatory Agency (MHRA) in the UK. Inceptua AB will continue the work to advance the commercial plans for Apealea.

[For More Information:](#)

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[About Vivesto AB](#)

Vivesto is a specialty pharma company that develops new treatment options for patients suffering from difficult-to-treat cancer. The company has a growing portfolio of clinical-stage projects targeting advanced cancer. Apealea® (paclitaxel micellar) is made available to patients with ovarian cancer through a partnership with Elevar Therapeutics, Inc. Other development programs include Cantrixil, a clinical program in long-developed ovarian cancer, and Docetaxel micellar being developed for metastatic prostate cancer. Vivesto's proprietary and patented technology platform is developed to improve the water solubility, efficacy and safety of pharmaceuticals. The company's shares are traded on Nasdaq Stockholm (ticker: VIVE). Visit www.vivesto.com for more information about Vivesto.

Attachments

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