

Inceptua receives formal approval of the transfer of Oasmia's marketing authorization for Apealea®

Solna, Sweden 10 December 2021 – Oasmia Pharmaceutical AB (Oasmia), an oncology-focused specialty pharmaceutical company, today announces that the transfer of its marketing authorization for Apealea® (paclitaxel micellar) to Inceptua AB has received approval from the European Commission and the UK Medicines and Healthcare products Regulatory Agency (MHRA).

As the new marketing authorization holder, Inceptua will assume full regulatory responsibility for Apealea® in the EU, Norway, Iceland, Liechtenstein and the UK.

Apealea® is approved in combination with carboplatin for the treatment of adult patients with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer.

Francois Martelet, Chief Executive Officer, Oasmia, commented: *"This marketing authorization transfer is in line with Oasmia's strategy, to commercially launch Apealea® through partners and build a diversified pipeline focused on hard-to-treat and late-stage cancers using different mechanisms of action. We anticipate receiving our first royalties on Apealea® sales during 2022 following commercial product launches in several key European markets."*

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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. Apealea® (paclitaxel micellar) is being made available to ovarian cancer patients through a partnership with Elevar Therapeutics, Inc. Development programs include Cantrixil, in clinical development for late-stage ovarian cancer, and docetaxel micellar, in development for advanced prostate cancer. Oasmia has proprietary drug delivery technology designed to improve solubility, efficacy and safety. Oasmia's shares are traded on Nasdaq Stockholm (OASM). To find out more about Oasmia please visit www.oasmia.com.

About Inceptua Group

Inceptua Group is a specialty pharmaceutical company and global service partner.

Inceptua Pharma commercializes and markets orphan and specialty care products and have the expertise and capabilities to supply unlicensed medicines globally.

The service business units, Inceptua Clinical Trial Supply and Inceptua Early Access, support pharma and biotech companies with global clinical trial comparator sourcing, packaging, labelling, and distribution solutions and strategy, design and implementation of global early access programs (pre-approval, managed access, compassionate use).

Inceptua partners with life science companies of all sizes, drawing on over 20 years of industry experience, and has global operations with local offices across Europe, North America, and Asia.

Additional information is available at www.inceptua.com.

About Elevar Therapeutics

Elevar Therapeutics is a rapidly growing, fully integrated biopharmaceutical company built on the promise of elevating treatment experiences and outcomes for patients who have limited or inadequate therapeutic options. Elevar's lead proprietary drug candidates include rivoceranib (apatinib) and Apealea® (paclitaxel micellar). Rivoceranib, under the name apatinib in China, was developed by Hengrui in China and approved in China as a single agent for treatment of gastric cancer in 2014 and second-line advanced HCC in 2020. It has been granted Orphan Drug designation in the U.S., Europe and South Korea and has been clinically tested in over 1,000 patients worldwide in numerous cancer indications. Apealea® (paclitaxel micellar) is a non-Cremophor EL based formulation of paclitaxel that received marketing authorization by the European Commission in November 2018, making it Europe's first non-Cremophor EL formulation of paclitaxel approved for use in ovarian cancer. Elevar Therapeutics has offices in Utah, California, Ireland, and South Korea. Additional information is available at <https://elevartherapeutics.com/>.

About Apealea® (paclitaxel micellar)

Apealea® is a patented, water-soluble, intravenously injectable, non-Cremophor based formulation of paclitaxel that can be given without premedication such as steroids and with a shorter infusion time. Paclitaxel is a well-known chemotherapy agent used to treat breast, ovarian, lung, bladder, prostate, melanoma, and oesophageal cancer, as well as other types of solid tumour cancers. Cremophor-EL, is a formulation vehicle used for various poorly-water soluble drugs, including the anticancer agent paclitaxel and is associated with allergic reactions. Apealea® received marketing authorization by the European Commission in November 2018, making it Europe's first non-Cremophor-EL formulation of paclitaxel approved for use in ovarian cancer.

About Ovarian Cancer

Ovarian cancer is one of the most common female cancers affecting the primary reproductive organs¹. Globally, it is the third most common cancer among women and has the highest mortality rate^{2,3}. Although ovarian cancer has a lower prevalence in comparison with breast cancer, it is three times more lethal, and it is predicted that, by the year 2040, the mortality rate of this cancer will rise significantly^{4,5}. About half of the women who are diagnosed with ovarian cancer are 63 years or older and many of these patients are predisposed to age-related comorbidities, such as diabetes, which can influence treatment response and prognosis⁶.

1. American Cancer Society "About Ovarian Cancer." <https://www.cancer.org/cancer/ovarian-cancer/about/what-is-ovarian-cancer.html> Accessed November 24, 2020

2. Bray F, et al. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2018 Nov; 68(6):394-424.
3. Coburn SB, et al. International patterns and trends in ovarian cancer incidence, overall and by histologic subtype. *Int J Cancer.* 2017 Jun 1; 140(11):2451-2460.
4. Yoneda A, et al. Breast and ovarian cancers: a survey and possible roles for the cell surface heparan sulfate proteoglycans. *J Histochem Cytochem.* 2012 Jan; 60(1):9-21.
5. Bray F, et al. Global cancer statistics 2018: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA Cancer J Clin.* 2018 Nov; 68(6):394-424.
6. Minlikeeva, Albina N., et al. "History of hypertension, heart disease, and diabetes and ovarian cancer patient survival: evidence from the ovarian cancer association consortium." *Cancer Causes & Control* 28.5 (2017): 469-486.

Attachments

[Inceptua receives formal approval of the transfer of Oasmia's marketing authorization for Apealea®](#)