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PRESS RELEASE

European Medicines Agency validates Oasmia Pharmaceutical AB's application to add efficacy data to the approved Apealea® product information

Efficacy data from sub-group analysis for Apealea show significant advantage with regards to progression free survival in patients with first relapse.

Uppsala, Sweden, January 15, 2019 – Oasmia Pharmaceutical AB (NASDAQ: OASM) AB today announce that the European Medicines Agency (EMA) has validated a type II variation application to add efficacy data to the Apealea product information. Validation of the application confirms that the submission is complete and that the EMA assessment process begins. Based on the EMAs procedural timelines, Oasmia anticipates an opinion from the Committee for Medicinal Products for Human Use (CHMP) by end of Q1 or beginning of Q2 2019.

The application is based on subpopulation data (n=599) from the OAS-07OVA study and aims to provide treating physicians with efficacy data for Apealea in combination with carboplatin for the approved indication; adult patients with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer. The current efficacy data describes the population in OAS-07OVA that also included patients with several disease relapses (n=789).

About the subpopulation analysis submitted as a type II variation:

The marketing authorisation approval for Apealea in the EEA was based on study OAS 07OVA conducted on 789 randomized patients with disease relapse. The results of the subpopulation analysis of patients experiencing their first relapse were based on 301 patients (Apealea arm) and 298 patients (Comparator arm) being part of the OAS-07OVA study. The results show that there is a statistically significant advantage for Apealea with regards to progression-free survival.

Key efficacy results in patients with their first relapse in the intention-to-treat population from the pivotal randomized clinical trial OAS-07OVA

	Progression-free survival (PFS) (N=301)		Overall survival (OS) (N=298)	
Hazard ratio, HR[1] (95% CI)	0.80 (0.66-0.97)		0.98 (0.79-1.21)	
	Apealea[2]	*CrEL-paclitaxel*[2]	*Apealea*[2]	*CrEL-paclitaxel*[2]
Median, months (95% CI)	10.3 (10.1-11.1)	10.0 (9.6-10.2)	24.7 (21.9-28.0)	23.4 (20.5-26.7)

[1]A longer PFS or OS for Apealea compared to Cremophor-EL (CrEL)-formulated paclitaxel is indicated by a HR less than 1.0.
[2]In combination with carboplatin.

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Notes to editors:

About epithelial ovarian cancer
Ovarian cancer is the seventh most common cancer in women. Approximately 239,000 women are annually diagnosed with ovarian cancer globally and 152,000 dies from the disease. Epithelial ovarian cancer is the most common form and accounts for about 90% of ovarian cancers. The disease is often diagnosed at an advanced staged since it has no symptoms at early stages. The five-year survival rate (i.e. survival of patients with ovarian cancer compared to survival in the general population at the same age) for ovarian cancer has been estimated to 38% in Europe. During 2018, approximately 68,000 women will be diagnosed with ovarian cancer in Europe and 45,000 are predicted to die from the disease. Carboplatin and paclitaxel are common chemotherapy drugs for treatment of ovarian cancer and are often used in combination.

About Apealea
Apealea is a Cremophor- and albumin-free formulation of the well-known cytostatic paclitaxel combined with Oasmia's excipient technology XR17. Paclitaxel is one of the most widely used anticancer substances and is included in the standard treatment of a variety of cancers such as lung cancer, breast cancer and ovarian cancer. Apealea consists of a freeze-dried powder, which is dissolved in conventional solutions for infusion.

About Oasmia Pharmaceutical AB
Oasmia Pharmaceutical AB (NASDAQ: OASM) develops, manufactures, markets and sells new generations of drugs in the field of human and veterinary oncology. The company's product development aims to create and manufacture novel nanoparticle formulations and drug-delivery systems based on well-established cytostatics which, in comparison with current alternatives, show improved properties, reduced side-effects, and expanded applications. The company's product development is based on its proprietary in-house research and company patents. Oasmia is listed on NASDAQ Capital Markets (OASM.US), Frankfurt Stock Exchange (OMAX.GR, ISIN SE0000722365) and NASDAQ Stockholm (OASM.ST).

This information is information that Oasmia Pharmaceutical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08.30 CET on January 15, 2019.