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PRESS RELEASE

**Oasmia Pharmaceutical Receives Positive CHMP Opinion for Apealea® (paclitaxel micellar) in the European Union**

**Apealea receives positive CHMP opinion in the European Union for treatment of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer in combination with carboplatin in first relapse**

Uppsala, Sweden, September 21, 2018 – Oasmia Pharmaceutical AB (NASDAQ: OASM) today announce that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending approval of Apealea in combination with carboplatin for treatment of adult patients with first relapse of platinum-sensitive epithelial ovarian cancer, primary peritoneal cancer and fallopian tube cancer. The CHMP considers that the product Apealea in combination with carboplatin has a positive benefit-risk balance and is considered approvable for the above-mentioned indication.

The CHMP's positive opinion will now be considered by the European Commission. If the CHMP opinion is affirmed, the European Commission will grant a centralized marketing authorization with unified labelling that is valid in 28 countries of the European Union (EU), as well as the European Economic Area members, Iceland, Lichtenstein and Norway.

The CHMP recommendation is based on clinical trials including the pivotal study OAS 07OVA. This study showed that the risks of disease progression or death after Apealea treatment in combination with carboplatin are similar as after Cremophor EL (CrEL)-formulated paclitaxel in combination with carboplatin.

Key efficacy results in the per protocol population from the pivotal randomized clinical trial OAS-07OVA

	Progression-free survival (PFS) (N=644)		Overall survival (OS) (N=644)	
Hazard ratio, HR <sup>1</sup> (95% CI)	0.86 (0.72-1.03)		0.95 (0.78-1.16)	
Median, months (95% CI)	<i>Apealea</i> <sup>2</sup> 10.3 (10.1-10.7)	<i>CrEL-paclitaxel</i> <sup>2</sup> 10.1 (9.9-10.2)	<i>Apealea</i> <sup>2</sup> 25.7 (22.9-28.1)	<i>CrEL-paclitaxel</i> <sup>2</sup> 24.8 (21.7-27.1)

<sup>1</sup>A longer PFS or OS for Apealea compared to CrEL-formulated paclitaxel is indicated by a HR less than 1.0.

<sup>2</sup>In combination with carboplatin.

The most frequently reported adverse reactions after Apealea treatment in combination with carboplatin ( $\geq 10\%$ ) were neutropenia, anorexia, peripheral sensory neuropathy, neuropathy peripheral, diarrhea, nausea, vomiting, alopecia, arthralgia, myalgia, asthenia, fatigue and infusion site reaction.

**For more information:**

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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).

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*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 13.10 CET on September 21, 2018.*