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PRESS RELEASE

Oasmia Pharmaceutical AB receives positive opinion from the European Medicines Agency to add efficacy data to the approved Apealea® product information

Uppsala, Sweden, March 25, 2019 – Oasmia Pharmaceutical AB (NASDAQ: OASM) today announce that the European Medicines Agency (EMA) has adopted a positive opinion recommending approval of a type II variation application to add efficacy data to the Apealea product information.

The marketing authorisation approval for Apealea in the EEA was based on the phase III pivotal study OAS-07OVA. The study was conducted on 789 randomized patients with relapse of ovarian cancer disease that were treated with paclitaxel in combination with carboplatin. The results of the subpopulation analysis of the patients corresponding to the approved indication, *i.e* patients experiencing their first relapse, were based on 301 patients (Apealea arm) and 298 patients (Comparator arm).

The positive opinion of the application allows the product information to present all available efficacy data for Apealea for the approved indication in addition to the data describing the entire population. This change may be implemented after completion of the review process of the translation into all EU languages (and Norwegian and Icelandic) by the end of April 2019.

– This provides complete transparency to the physicians, as well as patients, regarding differences in efficacy between Apealea and solvent-based paclitaxel, says Mikael Asp, CEO

Information on subgroup analysis by relapse:
Subgroup analyses were conducted to investigate efficacy by relapse (first and second) in the per protocol (PP) and the intention-to-treat (ITT) populations. Progression free survival (PFS) and overall survival (OS) results in the PP population are presented in the tables below. In the intention-to-treat population, the hazard ratios (HR) for PFS in the subgroups of patients with first relapse and second relapse were 0.80 (95% confidence interval (CI): 0.66;0.97) and 1.04 (95% CI: 0.74;1.47), respectively. The hazard ratios for OS in patients with first and second relapse were 0.98 (95% CI: 0.79;1.21) and 1.18 (95% CI: 0.79;1.75), respectively. Thus, the results in the subgroup of patients with first relapse are consistent with the results in the overall population and in addition, there was an indication of PFS benefit for Apealea.

Progression free survival (PFS) of subgroup analysis by relapse in the per-protocol (PP) population:

		Apealea			Solvent-based paclitaxel			
	***N* (all)**	***n***	**events**	**Median (months)**	***n***	**events**	**Median (months)**	**HR* (95% CI)**
All patients								
PP	644	311	239	10.3	333	270	10.1	0.86 (0.72-1.03)
First relapse								
PP	497	240	180	10.3	257	209	10.1	0.82 (0.67-1.00)
Second relapse								
PP	147	71	59	9.9	76	61	10.1	1.01 (0.69-1.46)

* A longer PFS for Apealea compared to solvent-based paclitaxel is indicated by a HR less than 1.0. Non-inferiority margin is 1.200.

Overall survival (OS) of subgroup analysis by relapse in the per-protocol (PP) population :

		Apealea			Solvent-based paclitaxel			
	***N* (all)**	***n***	**events**	**Median (months)**	***n***	**events**	**Median (months)**	**HR* (95% CI)**
All patients								
PP	644	311	179	25.7	333	206	24.8	0.95 (0.78-1.16)
First relapse								
PP	497	240	139	26.1	257	162	23.6	0.92 (0.73-1.16)
Second relapse								
PP	147	71	40	23.2	76	44	24.8	1.07 (0.68-1.68)

* A longer OS for Apealea compared to solvent-based paclitaxel is indicated by a HR less than 1.0. Non-inferiority margin is 1.185.

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).
