

# PRESS RELEASE

## 2018-07-27

# Status of Orphan designation of Apealea in the European Union

Uppsala, Sweden, July 27, 2018 – Oasmia Pharmaceutical AB (NASDAQ: OASM) herewith announces that Apealea was designated as an orphan medicine by the European Commission in 2006 and alongside the procedure of the application for assessing a Market Authorization, the Committee for Orphan Medicinal Products (COMP) carries out in accordance with normal practice an estimation whether the classification as Orphan medicine should be maintained. The designation as an orphan medicinal product is based on the prevalence of the condition (it should occur in less than 5 in 10,000 EU citizens) and the benefit expected from the new formulation. The demographic situation is ever changing and the EU gets an even older population. Women also live longer with the disease and it has been suggested that these changes may increase the prevalence of ovarian cancer. The most recent data from the Nordic countries show that the prevalence is now as high as 17.1 women out of 10,000 women. Considering among other facts this situation and after having had the possibility to present the data to the COMP, Oasmia has decided to withdraw its application for orphan medicine concerning Apealea.

Although the review of the status by the COMP is a routine part of all marketing applications for orphan medicinal products, the company's decision will not impact the review of the application by the Committee for Medicinal Products for Human Use (CHMP) who assess the marketing application.

#### For more information:

Julian Aleksov, Executive Chairman Tel: +46 18 50 54 40 E-mail: julian.aleksov@oasmia.com

#### 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. Common chemotherapy drugs used for the treatment for ovarian cancer

include cisplatin or carboplatin, and paclitaxel or docetaxel, which are most often given 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 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).

Information is also available at www.oasmia.com www.nasdaqomxnordic.com www.boerse-frankfurt.de twitter.com/oasmia

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 08.50 CET on July 27, 2018.