

# PRESS RELEASE

# Oasmia Pharmaceutical AB Provides Updates to Clinical Program Development

## OASM advances global commercialization efforts for all products

New York, February 24, 2016 – Oasmia Pharmaceutical AB (Nasdaq: OASM), a developer of a new generation of drugs within human and veterinary oncology, today announced updates on the clinical development of its family of products that it has continued to advance and commercialize in countries around the world:

- **Paclical**<sup>®</sup>/**Apealea**<sup>®</sup>. Last month, Oasmia announced that Paclical had been submitted for marketing authorization to the European Medicines Agency (EMA). Oasmia anticipates Overall Survival Data for this product, alternatively branded Apealea by the Company for use in Europe, during the second quarter of 2016 that it will add to the existing submission to EMA. The data resulting from this study will also be used as the basis for the Company's US submission to FDA. Discussions of label extension are ongoing and as a part of that, a dose-finding study of weekly administration in metastatic breast cancer patients has been completed and the results are currently under evaluation.
- **Docecal**<sup>®</sup>. The investigators' meeting for the safety and tolerance study with Docecal, the Company's next generation anti-cancer drug, was held as planned on December 11, 2015. Investigators and study nurses from the clinics participated and were given a presentation of the study as well as its design and procedures. The First Patient In study is planned for the first quarter of 2016 with a Phase I crossover pharmacokinetic study comparing Docecal to Taxotere commencing in the second quarter of 2016.
- Doxophos<sup>®</sup>/Doxophos Vet®. Oasmia submitted application for market approval in Russia and CIS in December 2015. For other markets, the company has planned a Phase I study with Doxophos, but has decided to await safety data resulting from its ongoing study in dogs. The dogs so far evaluated have not shown any signs of heart problems, often considered a common side effect of treatment using doxorubicin.
- Paccal Vet<sup>®</sup>. As Oasmia recently regained its global distribution rights from Zoetis, it has revised its treatment strategy for Paccal Vet. The Company has planned to change the product from a specialized treatment for a small group of veterinary oncologists, to a product that can be used in a large number of veterinary clinics. One step towards this goal is to introduce a lower dose which has less severe side effects and appeal to a broader market. The evaluation of the Phase III study in

dogs with mast cell tumors will begin shortly, and its results will most likely play a factor on how the indication will be utilized moving forward.

"It is extremely encouraging to see the Oasmia portfolio of human and animal oncology treatments continue to move forward in terms of their development and commercialization," said Julian Aleksov, Executive Chairman of Oasmia. "These treatments, built upon our patented XR17 technology, represent what we believe to be immediate and future solutions for how physicians and patients address various forms of cancer. As we develop and execute sales for these products, we are confident in the Company's long-term position among industry leaders."

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### Notes to editors:

### About the Apealea/Paclitaxel Market

The two leading paclitaxel-based products on the market are Taxol and Abraxane<sup>®</sup>, two widely used cancer drugs. Taxol indications are breast cancer, non-small cell lung cancer, pancreatic cancer, ovarian cancer and AIDS-related Kaposis sarcoma. Taxol generated \$1.6 billion in sales in 2000 alone, prior to losing its patent protection in 2001. In 2013, Taxol generated \$92 million in post-patent sales. Abraxane, which received FDA approval in 2005 for metastatic breast cancer, followed by approvals for lung non-small cell lung cancer (in 2012) and metastatic pancreatic cancer (in 2013), generated \$759 million in worldwide annual sales in 2013 and \$979 million in 2014.

#### About Apealea

Apealea is a Cremophor-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. It has orphan drug designation in the EU and the US.

#### About epithelial ovarian cancer

In 2012, 239,000 women were diagnosed with ovarian cancer globally. Epithelial ovarian cancers account for about 85% to 90% of ovarian cancers, and are the most aggressive and dangerous sub-type. In the EU, the five-year survival rate for ovarian cancer was 37.6% from 2000-2007 according to a study published in The Lancet. In 2012, there were 44,149 diagnosed cases of ovarian cancer in the EU, according to the European Cancer Observatory/International Agency for Research on Cancer; 29,758 of these women died of ovarian cancer. 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 Oasmia Pharmaceutical AB

Oasmia Pharmaceutical AB develops 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 USA (OASM.US), Frankfurt Stock Exchange (OMAX.GR, ISIN SE0000722365) and NASDAQ Stockholm (OASM.ST).

### **Oasmia Pharmaceutical AB Forward Looking Statements**

This announcement contains forward-looking statements. These statements are based on expectations in light of the information that is currently available, as well as assumptions that are subject to risks and uncertainties that could cause actual results to differ materially from such statements. These risks and uncertainties include, but are not limited to, domestic and international economic conditions, industry and market conditions, and changes of interest rate and currency exchange rate, in general, and completion and discontinuation of clinical trials, obtaining regulatory approvals, claims and concerns about product safety and efficacy, technological advances, domestic and foreign healthcare reforms, and changes of laws and regulations, in particular, with respect to each of Paclical. The company disclaims any intention or obligation to update or revise any forward-looking statements whether as a result of new information, future events or otherwise. This announcement contains information on pharmaceuticals (including pharmaceuticals under development) but is not intended to, and does not, make any representations, warranties or claims regarding the efficacy or effectiveness of these pharmaceuticals or provide medical advice of any kind.

Apealea and Paclical are registered trademarks of Oasmia Pharmaceutical. Cremophor is a registered trademark of BASF. Abraxane is a registered trademark of Celgene. Taxol is a registered trademark of Bristol-Myers Squibb. When "Taxol" is used in this press release, it refers to Taxol as well as to generic formulations of Taxol.

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"Oasmia is required under the Financial Instruments Trading Act to make the information in this press release public. The information was submitted for publication at 08.30 CET on February 24, 2016."