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**PRESS RELEASE**

**Oasmia Pharmaceutical Announces Positive Overall Survival Results from Phase III Study of Paclical/Apealea for Treatment of Ovarian Cancer**

**Overall Survival data from the Phase III study meets endpoint and demonstrates non-inferiority favoring Paclical/Apealea; will form basis for application seeking marketing approval in the United States anticipated for the end of 2016/2017.**

Uppsala, Sweden, April 27, 2016 --- Oasmia Pharmaceutical AB (NASDAQ: OASM), a developer of a new generation of drugs within human and veterinary oncology, today announced positive overall survival results for Paclical/Apealea in the Phase III study that included a total of 789 patients with epithelial ovarian cancer. These preliminary results showed non-inferiority between the two treatment groups of Paclical/Apealea in combination with carboplatin versus Taxol in combination with carboplatin. In fact, the overall survival in patients completing 6 treatment cycles was 25.7 months in patients that had received the Paclical/Apealea combination compared to 24.8 months in patients that had received the Taxol combination.

The results from the evaluation of the OS data confirm previous findings from June 2014 that the study had met the primary endpoint of Progression Free Survival (PFS) favoring Paclical/Apealea, and strengthens the positive risk/benefit profile for Paclical/Apealea published in October 2014. Earlier this year, Oasmia applied for marketing approval of Apealea (the alternatively branded name for Paclical) in the European Union for treatment of ovarian cancer. This overall survival data will be added to the EMA application and will form the basis of the marketing application to the FDA in the United States.

“It was expected that the analysis of the OS data would show non-inferiority and confirmation of the PFS results, two key factors for why we believe Apealea is an alternative to the presently available treatments of ovarian cancer,” said Margareta Eriksson, Vice President of Clinical Development at Oasmia Pharmaceutical. “Ovarian cancer is a fatal disease, one that is the fifth leading cause of cancer related deaths in women, and of which it is estimated that there will be over [22,000 new cases](#) in the United States in 2016. Today, the treatment is designed to postpone fatality and to improve the quality of life for these patients.”

“These results are very important for the further development of Oasmia’s product pipeline, as the new data will add value to Apealea’s application for marketing approval in the EU and facilitate the marketing approval process in the United States,” said Julian Aleksov, Executive Chairman of Oasmia Pharmaceutical. “With recent reports forecasting the global market for drugs treating ovarian cancer will [reach \\$1.71 billion](#) in 2019, there exists a largely unmet need for novel therapies in oncology. We believe that Paclical/Apealea has tremendous potential to take significant market share in all major markets as we continue to commercialize and distribute the product.”

The overall survival data is requirement for a marketing authorization based on non-inferiority in the USA and Oasmia plans to submit an application to the FDA for approval of Apealea for treatment of ovarian cancer in the end of 2016/2017.

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**About the market for paclitaxel-based cytostatics**

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, ovarian cancer and AIDS-related Kaposi 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.

\*Taxol is a term for various generics based on the Taxol formulation

**About Paclical/Apealea**

Paclical/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. Paclical/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 the Phase III clinical study of Paclical**

The Phase III open, randomized, multi-center study, which included in total 789 patients, was designed to compare the efficacy and safety between Paclical and Taxol, which is also a paclitaxel-based product. Both Paclical and Taxol were administered in combination with carboplatin.

Paclitaxel in combination with carboplatin, or any other platinum containing compound, has emerged as a standard in a first line setting in patients with epithelial ovarian cancer, and is used also as second line treatment, providing the patient had a response time of at least 6 months. These patients are defined as platinum sensitive.

The period from randomization to relapse or death (PFS) becomes shorter with the number of relapses, and hence treatment periods, that the patient goes through. A published study comparing the period of the first PFS with the second showed a difference of 7 months, 17.8 compared to 10.8 months.

The phase III study showed a PFS period of 10.3 months for Paclical + carboplatin compared to 10.1 months for Taxol + carboplatin. The result corresponds well with literature data from studies in platinum sensitive patients in second line treatment, e.g. 10.8 months (ref 1) and 9.4 months.

The study was designed to achieve the following primary objective:

PFS: to show non-inferiority of Paclical (250 mg/m<sup>2</sup>) vs Taxol (175 mg/m<sup>2</sup>, using computed tomography (CT) scans according to Response Evaluation Criteria in Solid Tumors (RECIST), as assessed by central review.

Inclusion criteria included patients who relapsed at least six months after end of first line or second line treatment including platinum based therapy. Paclical was administered as a one-hour intravenous infusion at its recommended dose of 250 mg/m<sup>2</sup>. Taxol was administered as a three-hour intravenous infusion at its recommended dose of 175 mg/m<sup>2</sup>. Both drugs were dosed in six three-week cycles.

Patients treated with Taxol received systemic pre-treatment with corticosteroids, antihistamines and H2 receptor antagonists. Patients treated with Paclical did not receive such treatment to the same extent. Carboplatin was given as an intravenous infusion starting 30 minutes after the end of the paclitaxel infusion. The carboplatin dose is based on kidney function measured as creatinine clearance ("5-6 AUC") that means that the variation in dose between patients is large, with a mean of approximately 625 mg/cycle, but it can be twice that much for an individual patient. After completing the treatment cycles, patients were followed until progression.

Overall survival data was calculated as the time from randomization into the study to day of death independent of reason. Patients left the study at disease progression and received other treatment, either as participants in a clinical trial or following the treatment recommendation of the country/clinic. The nature of this treatment is not known, but it is anticipated that as it is a randomized study, any difference regarding treatment of the two groups would be minimal.

### **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. 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, 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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Information is also available at [www.oasmia.com](http://www.oasmia.com) [www.nasdaqomxnordic.com](http://www.nasdaqomxnordic.com) [www.boerse-frankfurt.de](http://www.boerse-frankfurt.de) [twitter.com/oasmia](https://twitter.com/oasmia)

*"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 April 27, 2016."*