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PRESS RELEASE

Oasmia's Lead Human Product Paclical® Successfully Meets Primary Objective in Pivotal Phase III Clinical Study

Positive progression free survival data in patients with epithelial ovarian cancer

UPPSALA, Sweden, June 16, 2014 - The Swedish pharmaceutical company Oasmia Pharmaceutical AB (publ) today announced that its lead human product Paclical® (paclitaxel) has successfully met its primary objective according to the study design, showing non-inferiority between Paclical and Taxol – both combined with the chemotherapeutic carboplatin – regarding progression free survival (PFS).

The data show that Paclical, which has orphan designation for epithelial ovarian cancer in the EU and in the US, met the pre-defined requirement of non-inferiority compared with Taxol.
The Phase III open, randomized, multi-centre 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 study comparing the period of the first PFS with the second showed a difference of 7 months, 17.8 compared to 10.8 months (ref 1).

The 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 (ref 2).

"We are very excited by these results. Our patented XR-17 technology increases the solubility of the well-known cytostatic paclitaxel without the use of toxic solvents, which we believe facilitates the ease of administration and allows for higher doses than some of the other existing products on the market. We are pursuing a strategy to replace the use of these products in treating multiple types of cancer", commented Julian Aleksov, CEO and President of Oasmia.

The study was designed to achieve the following primary objective:

- PFS: to show non-inferiority of Paclical (250 mg/m2) versus Taxol (175 mg/m2) 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/m2. Taxol was administered as a three-hour intravenous infusion at its recommended dose of 175 mg/m2. 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. 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.

Oasmia will complete a clinical trial report in the second half of 2014, including a risk/benefit analysis. Furthermore, the study will compare PFS assessed with CT (RECIST) and the biomarker CA 125. The data will serve as the basis of a Marketing Authorisation Application to the European Medicines Agency (EMA), which the company intends to submit in early 2015.

"Also, we will continue to follow patients from the Phase III clinical trial to measure overall survival and expect to have results in the fourth quarter of 2014. Depending on these results, we will send in an application to the US Food and Drug Administration (FDA)", said Julian Aleksov.

For more information, please contact:
Mikael Widell, Vice President Communications
Mobile: +46 70 311 99 60
E-mail: mikael.widell@oasmia.com

Notes to editors:

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 OMX Stockholm (OASM) and the Frankfurt Stock Exchange (OMAX, ISIN SE0000722365). www.oasmia.com

About Paclical®
Paclical is a water-soluble formulation of the well-known cytostatic paclitaxel combined with Oasmia's excipient technology XR-17. Paclitaxel is one of the most widely used anti-cancer substances and is included in the standard treatment of a variety of cancers such as lung cancer, breast cancer and ovarian cancer. Paclical consists of a freeze-dried powder dissolved in conventional solution for infusion. It has orphan drug designation in the EU and the US.

About the Paclical market
The two leading paclitaxel-based products on the market are Taxol and Abraxane, two widely used cancer drugs. 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 (in 2012) and pancreatic cancer (in 2013), generated $427 million in worldwide annual sales in 2012 and generated $649 million in 2013.

In order to deliver paclitaxel, Taxol contains the solvent Cremophor EL. The toxicity of Cremophor EL limits the dose of Taxol that can be administered during a reasonable time, potentially limiting the efficacy of the drug. In addition, patients receiving Taxol require pre-medication with steroids and antihistamines to prevent the toxic side effects associated with the combination of paclitaxel and Cremophor EL.

Abraxane was developed as a Cremophor-free product containing paclitaxel suspended in human albumin. Because Abraxane contains no Cremophor EL solvent, Abraxane's recommended dosing enables the delivery of 50% more paclitaxel while maintaining a similar safety profile, and requires no routine pre-medication to prevent hypersensitivity reactions or the immediate allergic effects that often prevent or limit treatment. Like Abraxane, Paclical is free of Cremophor EL, but unlike Abraxane, Paclical does not contain human albumin.

About XR-17
XR-17 is Oasmia's proprietary excipient and is based on Vitamin A. It forms micelles that are between 20 and 60 nanometres in size. One property that makes XR-17 special is that it can also form micelles with water-soluble substances. This increases its potential uses significantly. Once XR-17 has delivered the encapsulated molecule or molecules to the target, the excipient is metabolized naturally. XR-17 facilitates the ease of administration and allows for higher doses than some of the other existing pharmaceutical products on the market, including cytostatics such as paclitaxel.

About epithelial ovarian cancer
Epithelial ovarian cancers account for about 85% to 90% of ovarian cancers, and are the most aggressive and dangerous sub-type. According to the National Cancer Institute, in 2011, the most recent year in which data is available, there were over 185,000 women living with ovarian cancer in the U.S. The five-year survival rate for ovarian cancer from 2004 to 2010 was 44.6%, and it is estimated that 21,980 women will develop and 14,270 women will die from ovarian cancer in 2014.

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, while 29,758 women died of ovarian cancer. In the U.S., 51% of women with ovarian cancer are diagnosed with stage III cancer, characterized by microscopically confirmed peritoneal metastasis outside the pelvis and/or regional lymph node metastasis. 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 Risk/Benefit analysis
When you do a risk/benefit analysis, you put together all the factors that can be negative to the patient (risk), for instance side effects, if a certain medicine is needed before the treatment, and negative effects of quality of life, with factors that affect the patient in a positive way (benefit), such as disease free period, shorter infusion time and positive effects on quality of life, thereby getting a full overview where the benefit has to be greater than the risk.

Information is also available at www.oasmia.com www.nasdaqomxnordic.com www.boerse-frankfurt.de 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 8.30, CET on June 16, 2014."

Ref 1: Harrison, Gore, Spring et al. Gynecol Omcol 2007; 106(3):469-475
Ref 2: Suh, Kim, Kim, and Kang. J Gynecol Oncol 2110: 21(3):209-218