2016-02-08

PRESS RELEASE

Oasmia Has Submitted a Marketing Authorization Application to the European Medicines Agency for Its Lead Cancer Product Apealea® (Paclical®)

Uppsala, Sweden – February 8, 2016. Oasmia Pharmaceutical AB (NASDAQ: OASM) today announced the submission of a marketing authorization application (MAA) to the European Medicines Agency (EMA) for its lead cancer product Apealea (also known as Paclical). Apealea is a new formulation of paclitaxel in nanoparticular form based Oasmia's XR-17 technology.

Apealea is a novel formulation of paclitaxel based on the patented excipient platform XR-17, which forms Cremophor®-free micellar nanoparticles with paclitaxel. The indication sought for Apealea is treatment of epithelial ovarian cancer in combination with carboplatin.

"After many years of significant efforts by everyone involved in this project, it is with great satisfaction that we are able to announce the regulatory filing of an application for marketing authorization of Apealea in the EU. Apealea, once approved, we believe would be able to take a share of the market for cytostatics in EU, which currently amounts to more than five billion Euros annually. Besides Abraxane is Apealea / Paclical the only paclitaxel drug which can be given in substantially higher doses", says Julian Aleksov, Executive Chairman of the Board of Oasmia Pharmaceutical AB.

Standard treatment of ovarian cancer is Taxol® in combination with carboplatin. Taxol is a combination formulation of paclitaxel in Cremophor EL (polyethoxylated castor oil) and ethanol. In order to avoid life threatening acute hypersensitivity reactions to Cremophor EL, treatment with Taxol requires extensive pre-medication with corticosteroids and antihistamines as well as a long infusion time. In the recently published results from Oasmia's pivotal Phase III study, Apealea showed a positive risk/benefit profile compared to treatment with Taxol; i.e. no need for pre-medication, the infusion time is one hour and possibly a reduced risk of experiencing neuropathy.

This marketing authorization application is based on results from a Phase III study with Apealea on epithelial ovarian cancer conducted in 16 countries. The primary objective of the Phase III clinical study, which consisted of an aggregate of 789 patients, was to show non-inferiority of Apealea (250 mg/m^2) versus Taxol (175 mg/m^2), both in combination with carboplatin. Tumour response and progression was assessed by external readers in a blinded fashion using computed tomography evaluated through RECIST (standardized response evaluation criteria in solid tumours).

The product has been approved in the Russian Federation since April 2015 and successfully launched by Oasmia's partner Pharmasyntez.

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

For media relations:
Eric Fischgrund
Tel: +1 (646) 699 1414
E-mail: eric@fischtankpr.com

Notes to editors:

About the Apealea/Paclitaxel Market
The two leading paclitaxel-based products on the market are Taxol and Abraxane®, 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 XR-17. 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.

Information is also available at www.oasmia.com www.nasdaq.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 08.30, CET on February 8, 2016."