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Positive Phase III Result From the Interim Analysis of the Study in Ovarian Cancer With Paclical(R)

UPPSALA, Sweden, Aug. 2, 2011 (GLOBE NEWSWIRE) -- Oasmia has completed an interim analysis of the ongoing Phase III study in ovarian cancer. The interim analysis, based on data from approximately 400 patients, showed the expected efficacy of Paclical® compared to the comparator, Taxol®. The results pointed towards a favorable efficacy for Paclical®. Based on these results, Oasmia will apply for marketing authorization for Paclical® within the European Union and some countries within the emerging markets, for the indication ovarian cancer.

Results from the interim analysis

Oasmia has developed a new approach of evaluation of a cancer drug that involves a biomarker, CA 125. This has not previously been used to evaluate the efficacy of a Phase III study. The design of the study is in accordance with the scientific advice received by the European Medicines Agency, EMA, in 2008. The interim analysis was performed by calculating the levels of CA 125 using a method developed in collaboration with experts in the field and in accordance to a scientific advice received by the EMA in 2008. CA 125 is used in clinical practice throughout the world to evaluate treatment response and progression of ovarian cancer.

The result from the interim analysis shows that Paclical is reducing CA 125 to the same level as Taxol. Oasmia will now continue the statistical analysis of e.g. time to response and proportion of responders based on CA 125, and evaluates the safety data from the patients that were included in the interim analysis. The study continues to collect data on time to progression.

The results from the interim analysis will provide the basis for submission for marketing authorization. The filing process will start immediately. The ongoing clinical study will continue as planned to collect additional data on e.g. progression free survival and overall survival.

About CA 125

CA 125 (Cancer Antigen 125) is a protein, often elevated in women with ovarian cancer. It is a blood test and the analysis of CA125 is used in clinical practice to evaluate the treatment of ovarian cancer. An increased value in a woman previously diagnosed with ovarian cancer is usually an indication of progression.
Oasmia has, in close collaboration with experts in the field, developed a method to evaluate the efficacy of treatment utilizing repeat measurements. Imaging a curve connecting all the values and the space below the curve as an area (area under curve), it will be possible to compare the area during treatment with the area before treatment. This method will consider not only how low the values will be but also how quickly the patient responds to treatment.

About the ongoing Phase III study with Paclical®

The study is carried out at about 80 clinics in 16 European countries and is estimated to include 650 patients. The comparator, Taxol®, is administered as 175 mg/m\(^2\) given as a 3-hour infusion and the patients receive the recommended pre-treatment according to clinical practice. The dose of Paclical® is 250 mg/m\(^2\) given as a 1-hour infusion and pre-medication is not necessary. Both drugs are administered in combination with carboplatin since Taxol® in combination with carboplatin is a standard treatment for ovarian cancer. The results are expected to form the basis for the company application for market authorization in EU, USA and ROW.

The comparator, Taxol®, needs excessive pre-medication to avoid the hypersensitivity reactions triggered by the solubilizer Cremophor® EL. Paclical® is water soluble, based on Oasmia’s development XR-17. No pre-medication and a shorter infusion time compared to Taxol® are looked upon by the patient as a great advantage for Paclical®.

Paclitaxel, the active component in both Taxol® and Paclical®, is part of the pharmaceutical group taxanes. Taxanes is an important group within cancer treatment that also contains the well-used cytostatic Taxotere® (docetaxel). The world market for taxanes is estimated to amount to 5.1 billion USD during 2009. In 2005, taxanes used for the treatment of ovarian cancer generated a turnover of 238 million USD. In addition to ovarian cancer, Taxol® is approved for treatment of e.g. breast cancer, lung cancer, head and neck cancer, and Kaposis sarcoma.

About interim analysis

An interim analysis is a statistical analysis performed before the study is completed. It is defined before start of the study and is done for two main reasons 1) to stop the study 2) to use the results in the application for marketing authorization. Oasmia has the latter reason to perform the interim analysis. However, the study will continue to recruit patients and collect data from all patients, e.g. on time to progression and overall survival.

About Paclical®

With the retinoid based unique platform XR-17, Oasmia has managed to develop a water soluble formulation of paclitaxel that does not require premedication. The formulation also has an improved side effect profile compared to Taxol®. The main indications are ovarian cancer and lung cancer.

About ovarian cancer
Ovarian cancer is a disease with few and unspecific symptoms at its early stages, therefore difficult to detect. Unlike certain other cancer diseases the number of patients diagnosed with ovarian cancer increases every year. Ovarian cancer is most often diagnosed in women over 50 years of age, but younger women are also affected. The annual incidence of new diagnosed cases is approximately 125 000 women in EU alone.

**About Oasmia**

Oasmia Pharmaceutical AB develops a new generation of drugs within human and veterinary oncology. The product development aims to manufacture novel formulations based on well-established cytostatics which, in comparison with current alternatives, show improved properties, a reduced side-effect profile and an expanded therapeutic area. The product development is based on in-house research within nanotechnology and company patents. The company was registered in 1999 and is located in Uppsala, Sweden.

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