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## PRESS RELEASE

Oasmia Pharmaceutical's **drug** candidate Paclical® shows promising results in patients with severe cancer.

In an initial study with Paclical® in humans carried out by Oasmia Pharmaceutical AB, Uppsala, Sweden, the maximum tolerable dose of the candidate was set to 250 mg/m<sup>2</sup>. In total 34 patients with advanced cancers were treated. No unexpected side-effects or hypersensitivity reactions were observed.

In the first Phase I/II study, which was performed in Sweden, both men and women were treated. Paclical® **was administered as three treatment cycles at 3 week's interval. The first dose was low, 90 mg/m<sup>2</sup> and was increased successively to a maximum dose of 275 mg/m<sup>2</sup>.** The adverse events which occurred indicated that the dose was too high. As expected, no hypersensitivity reactions were seen.

All dosages of Paclical® including 250 mg/m<sup>2</sup> were well tolerated by most patients. The adverse events that were reported were expected at treatment with paclitaxel which Paclical® contains. A stabilisation of the cancer diseases was seen in about half of the patients treated with 3 cycles, which is encouraging considering the severity of the disease in these patients. The dose of Paclical® in planned studies will be 250 mg/m<sup>2</sup> for 6 cycles. As an example, a common regiment for Taxol® is 175 mg/m<sup>2</sup> for 6 cycles.

Oasmia now conducts a study in patients with ovarian cancer will answer the question whether 250/mg<sup>2</sup> of Paclical® is more efficacious than 175 mg/m<sup>2</sup> of Taxol®.

Paclitaxel, the active compound in Paclical® has been used against various kinds of cancers for more than 15 years. The drawback of the drugs containing paclitaxel on the market is that they contain an excipient consisting of castor oil and ethanol (Cremophor® EL). Cremophor® EL is detrimental and associated with a number of adverse events, e.g. hypersensitivity reactions that can be anything from rash to severe shortness of breath. Currently, premedication is mandatory to reduce adverse events associated with Cremophor® EL.

One of the many difficulties in treating cancer with cytostatic agents is that as the cancer cells are destroyed, healthy cells such as white blood cells are also affected. The challenge is to give a dose high enough to kill the cancer cells but at the same time avoid reduction of the number of white blood cells to a level at which the patient is at risk of infections.

A problem faced with e.g. Taxol® is that the patient is in danger of adverse events from both paclitaxel and Cremophor® EL. There is a risk that the adverse events of Cremophor® EL will decide the dose. An excipient which does not cause adverse events on its own would make it possible to administer higher doses of paclitaxel and thus obtain a better and more efficacious treatment.

Oasmia Pharmaceutical AB has developed a novel nanotechnological excipient that resembles Vitamin A (XR-17). Paclical® consists of paclitaxel dissolved in XR-17.

#### About Paclical®

With the retinoid based unique platform XR-17, Oasmia has managed to produce a water soluble formulation of Paclitaxel (Paclical®), that does not require premedication and abolish Cremophor® EL related side effects. The main indication is ovarian cancer. Other planned indications are lung cancer (NSLC) and malignant melanoma.

#### About Oasmia

Oasmia Pharmaceutical AB develops second and third generation cancer drugs based on nanotechnology for human and veterinary use. The broad portfolio is focused on oncology and contains several promising products in clinical and pre-clinical phase. Oasmia cooperates with leading universities and other biotech companies to discover and optimize substances with a favourable safety profile and better efficacy. The company was founded in 1998 and is based in Uppsala, Sweden.

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For more information, please contact: Maria Lundén, Head of Public Relations, Oasmia Pharmaceutical AB. E-mail: [press@oasmia.com](mailto:press@oasmia.com) Phone: +46 (0) 18 50 54 40. Information is also available at [www.ngm.se](http://www.ngm.se) and [www.oasmia.com](http://www.oasmia.com)