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## PRESS RELEASE

FDA grants Oasmia Pharmaceutical Expedited Review Status (ERS) for Paclical® Vet

Oasmia has been granted Expedited Review Status (ERS) **for the company's** Animal Health product candidate. The company also changes the name of the candidate from Paclical® Vet to Paccal® Vet in order to use the same name world-wide.

The center for Veterinary Medicine, Food and Drug Administration in the United States has granted to Oasmia Pharmaceutical, Uppsala, Sweden, the product Paclical® Vet Expedited Review Status (ERS).

The US Food and Drug Administration Center for Veterinary Medicine grants Expedited Review Status (ERS) to certain products classified as important advances in animal health receive priority review beginning at the Investigational New Animal Drug (INAD) stage, but with no diminished standards for data quality or evaluation.

ERS is reserved only for products that FDA believes represent an important therapeutic gain. In most cases this is restricted to drugs that are indicated for a life-threatening or severely debilitating disease for which there is no other approved treatment available.

Because of the importance of these products to animal health, the FDA review time is half as long as those assigned to products without ERS. Normally, the review time assigned to a submission is **180 days. Products under ERS will have a review "clock" of 90 days. In theory,** this should significantly shorten the time to approval.

- It is a very positive and important achievement for us, since it will shorten the time to registration significantly. It will benefit our ongoing phase III study in the US and EU a great deal and an earlier launch on the very important US market, says Julian Aleksov, CEO of Oasmia.

Due to European approval of a new name, Oasmia changes the name to Paccal® Vet. The intention is to have same name world-wide. An application for name change is submitted in the USA.

For more information about ERS: [http://www.fda.gov/cvm/Policy\\_Procedures/3135.htm](http://www.fda.gov/cvm/Policy_Procedures/3135.htm)

### About Paccal® Vet

Paccal® Vet is a water soluble, solvent free nanoparticle formulation, based on the well-known cytotoxic substance paclitaxel. Paccal® Vet's unique properties are based on **Oasmia's nanotechnological formulation and micellar model XR-17**, which is protected by international patents. The new Oasmia platform means that paclitaxel is water-soluble, resulting in abolishing Cremophor EL related toxicity, that no premedication is necessary, infusion times can be shortened and infusion procedure can be made more effective.

## 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)