



2010-03-01

PRESS RELEASE

## Last patient out (LPO) for Paccal® Vet Phase III study

Oasmia Pharmaceutical AB, Uppsala, Sweden, today announces that the last patient in the company Phase III study with Paccal® Vet has completed the last treatment cycle and the evaluation is complete. The clinical data analysis has now begun. Preliminary results are expected in the spring of 2010.

The study is a blinded and controlled study where dogs with skin cancer has been treated with Paccal® Vet or Lomustine (CCNU). The patients have been randomly allocated to one of the two treatments. The parameters investigated in the study are how well the patients have responded to treatment and what kind of side-effects have been present.

- This is an important milestone in this extensive study, says Henrik von Euler, Chief Medical Officer at Oasmia Animal Health. The treatment of the patients has been completed and we can now focus in the data analysis. Results are expected during the spring of 2010.

## Market size

There are in total about 140 million dogs in the USA, EU and Japan today.<sup>[1]</sup> The number of dogs and cats is growing considerably faster than the number of inhabitants in these countries. Another fact is that these animals are growing older, which increases the cancer risk. About 40 to 50 percent of the dogs older than eight years will be affected by cancer. In the USA alone, there are about 300,000 – 500,000 dogs where treatment with cytostatics is an option.<sup>[2]</sup> Oasmia estimates that Paccal® Vet will have a global market potential within three to five years of between 500 to 700 MUSD<sup>[3]</sup>.

## About Paccal® Vet

With the retinoid-based, unique platform XR-17, Oasmia has managed to produce a water-soluble formulation of Paclitaxel (Paccal® Vet) that does not require premedication and eliminates Cremophor® EL-related side effects. Two clinical trials have been performed in client-owned dogs with tumors refractory to standard treatment. The results are very promising, both regarding tolerability and tumor response. Paccal® Vet has received designation for Minor Use status from the office of MUMS within the US Food and Drug Administration Center for Veterinary Medicine.

---

<sup>[1]</sup> Tuft University E-news, Nick Dodman 2009.

<sup>[2]</sup> Market potential based on published cancer incidence (Withrow S J and D M Vail (Eds) Small Animal Clinical Oncology, 4th ed, 2007, Saunders Elsevier, Missouri, US) and on the company's own market analysis

<sup>[3]</sup> The estimation is based on information from discussions with pharmaceutical companies, the cancer incidence in dogs and an average price for cancer treatment of dogs with surgery or other alternative treatment amounting to between \$4 000 and \$4 500 today. The estimation includes spill-over effects, that the pharmaceutical is used for treatment of other indications.

- Oasmia will be eligible to request conditional approval, to market Paccal® Vet before collecting all necessary efficacy data, but after proving the drug is safe. Conditional approval would allow Oasmia to market Paccal® Vet for up to five years while collecting the required effectiveness data.
- Following FDA approval, designated new animal drugs are granted seven years of marketing exclusivity, which means Oasmia would face no competition in the marketplace for the approved use of the drug for that time.

Paccal® Vet also has received Expedited Review status, a category reserved for products that have the potential to provide important advances in animal health. Expedited Review shortens the amount of time allotted for FDA-CVM to evaluate the safety and manufacturing data that must be accepted prior to applying for conditional approval.

#### About mastocytoma (Skin cancer)

Mastocytoma is a malignant form of cancer, originating from the mastocytom cells of the skin. The disease is graded from I - III depending on the seriousness of the disease. This form of cancer accounts for approximately 20% of all malignant skin tumors in dogs. Today, the most common form of treatment is surgery, although chemotherapy developed for human use is also used. Unfortunately, surgery as a treatment of advanced tumors is mostly ineffective, and euthanasia is often the only remaining alternative.

#### 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 favorable safety profile and better efficacy. The company name was registered in 1999 and is based in Uppsala, Sweden.

#### *Disclaimer*

*This press release includes forward-looking statements that involve a number of risks and uncertainties, the outcome of which could materially and/or adversely affect actual future results and the trading price of Oasmia's securities. Specifically, the risks and uncertainties that could affect the development of Paccal® Vet include risks associated with preclinical and clinical developments in the biopharmaceutical industry in general, and with Paccal® Vet in particular, including, without limitation, the potential for Paccal® Vet to be proved safe and effective (or to achieve response rates) for the treatment of the indications noted in this press release or any other indication, determinations by regulatory, patent and administrative governmental authorities, the potential that Paccal® Vet will not produce high rates of complete remission in patients with mastocytoma, the possibility that the registration trial for Paccal® Vet as a treatment for mastocytoma in dogs will not occur, the possibility that the U.S. Food and Drug Administration will not approve a phase III registration strategy for Paccal® Vet if proposed by Oasmia, the potential that Abbott will not exercise its distribution rights, Oasmia's ability to continue to raise capital as needed to fund its operations, competitive factors, technological developments, and costs of developing, producing and supplying Paccal® Vet. Except as may be required by law, Oasmia does not intend to update or alter its forward-looking statements whether as a result of new information, future events or otherwise.*

---

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)