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PRESS RELEASE

Oasmia Pharmaceutical aims for worldwide registration with a pivotal study on Paccal® Vet

Oasmia Pharmaceutical AB, Uppsala, Sweden is conducting a clinical study on mast cell tumours in dogs. The study will form the base for a registration submission of the first cytotoxic drug on the veterinary market ever.

The study is approved both by the FDA (US) and the EMEA (EU). The FDA has granted Oasmia expedited review which means a much faster approval process. So far the study has recruited 30% of the dogs to be included and the results are planned to be reported H2 2009.

With the large market of pet dogs that are diagnosed and managed with cancer estimated to be over 1 million per year only in the US (*Chand Khanna 2008*) the recruitment rate will be fast in this Phase III trial as this skin tumour is very common. There are over 135 million dogs in the US and EU.

The Phase III trial is a comparative randomized controlled blinded multi centre study on mast cell tumours in dogs grade II and III. Currently 19 sites in the US and 7 sites in the EU are participating, including both major private cancer specialist clinics as well as academic sites on both continents. There has been a great interest to participate among veterinary cancer specialists, including many world leaders in mast cell tumours.

The trial is comparing treatment response to either Paccal® Vet or CCNU (Lomustine). The published response to CCNU in mast cell tumours in dogs are 42% (evaluated in 19 dogs). The progression free survival was 77 days on average.

- This is a big step towards registration of the first chemotherapeutic drug in veterinary medicine. The results from prior studies with Paccal® Vet indicate that there is a good chance to show superiority against the comparator (CCNU), says Dr Henrik von Euler, study coordinator of two previous studies with Paccal® Vet in dogs with cancer, including mast cell tumours.

In a recently conducted multi centre open arm trial in dogs with grade II and III mast cell tumours with Paccal® Vet. Preliminary results show an overall response in 23 dogs treated 3 cycles of 69.5 % with a progression free survival of 235 days on average.

Reference: REF Translation of new cancer treatments from pet dogs to humans, Melissa Paoloni and Chand Khanna Nature reviews cancer feb 2008, 147-156.

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 abolish 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. Moreover, the studies show that the findings in the dog are supporting parallel trials in humans, regarding pharmacokinetics and reported side effects. The studies therefore supports the further development towards a registration of the first cytotoxic drug on the large cancer market for companion animals, as well as serves as a model for human oncology.

About mastocytoma (Skin cancer)

Mastocytoma is a malignant form of cancer, originating from the mastocytom cells of the skin. The disease is graded I - III depending on the seriousness of the disease. This form of cancer accounts for approximately 20 % of all malignant skin tumours 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 e.g. grade III tumours 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 favourable safety profile and better efficacy. The company was founded in 1998 and is based in Uppsala, Sweden.

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