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PRESS RELEASE

Oasmia: FDA grants Paccal® Vet Minor Use status

Oasmia Pharmaceutical, Uppsala, Sweden, has received a notification of Minor Use status (MUMS) for Paccal® Vet. MUMS provides several benefits including a seven year market exclusivity when registered and eligibility for conditional approval.

Paccal® Vet, Oasmia's investigational product to treat cancer in dogs, has received designation for Minor Use status by the US Food and Drug Administration Center for Veterinary Medicine. Minor use designation provides several benefits, among others:

- 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 data.

- Following FDA approval, designated new animal drugs are granted seven years of marketing exclusivity, which means Oasmia would face no generic competition in the marketplace for the approved use of the drug for that time.

Minor Use status[1] for animal drugs is similar to Orphan Drug status for human drugs. This designation applies to the indication "for the treatment of non-resectable Grade II and III mast cell tumors that have not received previous therapy, except corticosteroids, in dogs." FDA made their decision after assessing the data which Oasmia's previously submitted concerning the scientific rationale and development plan for the product candidate.

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

- We are very pleased to have received MUMS designation in which conditional approval can be utilized. Each day in which we can reduce the time to the market is extremely valuable for Oasmia and its US partners. The US market is the largest for Paccal® Vet with about 100 000 dogs annually suffering from mast cell tumors, says Julian Aleksov, CEO of Oasmia in a comment.

[1]More information in regards to Minor Use can be found at FDA's homepage at: http://www.fda.gov/cvm/minortoc.htm

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 name was registered in 1999 and is based in Uppsala, Sweden.

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