2011-06-13

PRESS RELEASE

FDA grants Paccal® Vet Minor Use designation for squamous cell carcinoma

Oasmia Pharmaceutical, Uppsala, Sweden, has received Minor Use status (MUMS) for Paccal® Vet in the indication Squamous cell carcinoma. MUMS-status 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 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 resectable and non-resectable squamous cell carcinoma." FDA made their decision after assessing the data which Oasmia's previously submitted concerning the scientific rationale and development plan for the product candidate.

- We are very pleased to have received MUMS designation for Squamous cell carcinoma. It enables us to widen Paccal® Vet's area of use for and present veterinarians with a more versatile product, says Julian Aleksov, CEO of Oasmia.

About Paccal® Vet

Paccal® Vet is a novel formulation composed of Oasmia Pharmaceutical's patented excipient XR-17 and the anti-cancer substance paclitaxel. XR-17 is a nanotechnologically produced model which can be used in order to improve the solubility of substances, such as paclitaxel, one of the most frequently used chemotherapeutic substances in the world. Many chemotherapeutic drugs based on paclitaxel are usually dissolved in lipid soluble formulations, which are associated with a range of side-effects, both in humans and dogs. In humans they can usually be controlled with pre-medication, in dogs the reaction is often fatal despite pre-medication. Paccal® Vet lacks the lipid soluble formulation-related side effects.

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

About Squamous cell carcinoma

Squamous cell carcinoma (SCC) is a malignant epithelial cancer in the skin. It is the second most common skin cancer in the dog (up to 20% of skin tumors). Today, the most common form of treatment is surgery, although off-label chemotherapy registered for human use is sometimes used. There is no registered drug for use in dogs with this tumor. If the SCC is low differentiated (i.e. more aggressive and malignant) surgery is rarely curative and the tumor is highly metastatic. Without medical treatment such patients have a very short survival despite advanced surgery. In certain cases the tumors are situated where surgery cannot be performed without significant impairment of function and reducing the dog's quality of life significantly. Even here an efficient drug for canine SCC would be of great value to increase the survival and quality of life for the dogs suffering from this common and aggressive disease.

About Oasmia Pharmaceutical AB

Oasmia Pharmaceutical AB develops a new generation of drugs within human and veterinary oncology. The product development aims to manufacture novel formulations based on well-established cytostatics which, in comparison with current alternatives, show improved properties, a reduced side-effect profile and an expanded therapeutic area. The product development is based on in-house research within nanotechnology and company patents. The company was registered in 1999 and is located 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. German contact : Telefon: +46 (0) 18 50 54 40. Dr. Sönke Knop, Peggy Kropmanns, edicto GmbH, Frankfurt, Deutschland E-Mail: oasmia@edicto.de, Telefon: +49 (0) 69 90 55 05 51.
Information is also available at www.oasmia.com www.nasdaqomxnordic.com www.boerse-frankfurt.de