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PRESS RELEASE

FDA grants Paccal® Vet Minor Use designation for mammary tumors

Oasmia Pharmaceutical, Uppsala, Sweden, has received Minor Use designation (MUMS) for Paccal® Vet on the indication nonresectable stage III, IV or V mammary carcinoma. MUMS allows for 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 allows for the following provisions:

- 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 on the indication 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 nonresectable stage III, IV or V mammary 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. Oasmia has licensed exclusive US and Canadian commercialization rights for Paccal® Vet to Abbott's Animal Health division.

- This is very good news for Oasmia, as it enables us to apply for conditional approval. We view this designation as further confirmation of the solid concept behind Paccal® Vet, says Julian Aleksov, CEO of Oasmia.

[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

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. In humans they can usually be controlled with pre-medication, but in dogs the reaction is often fatal despite pre-medication. Paccal® Vet is free from the lipid soluble formulation-related side effects.

About Mammary tumors

Mammary carcinoma is the most common form of tumors forming in the mammary gland in mostly older intact (not spayed and neutered) dogs and cats, but also other mammals. It is specifically older female dogs which are affected. About 5 000 cases are reported in the US each year. The disease is terminal, and the animal dies within nine to twelve months if the disease is left untreated. The most common treatment is surgery.

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 share is listed on NASDAQ OMX Stockholm and the Frankfurt Stock Exchange.

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