Oasmia Receives FDA Conditional Approval For Its Lead Product Paccal Vet®-CA1

Conditional Approval of Paccal Vet-CA1 Gives Veterinarians Access to Proven Human Cancer Treatment Paclitaxel

UPPSALA, Sweden, Feb. 28, 2014 – The Swedish pharmaceutical company Oasmia Pharmaceutical AB (publ) today announced that the U.S. Food and Drug Administration (FDA) has conditionally approved Paccal Vet®-CA1 (paclitaxel for injection), providing veterinary oncologists with a new treatment option in the battle with canine mammary carcinoma and squamous cell carcinoma.

Paccal Vet-CA1 is the first veterinary drug to utilize paclitaxel, one of the most frequently used chemotherapeutics for the treatment of a wide range of cancers in humans for the past 20 years. Oasmia has signed an agreement with the global health care company Abbott which gives its Animal Health division the exclusive worldwide distribution rights to Paccal Vet-CA1, excluding Russia, Japan and the Commonwealth of Independent States (CIS).

“The conditional approval of Paccal Vet-CA1 is a big step forward for veterinary cancer treatment,” commented Julian Aleksov, chief executive officer of Oasmia. “In addition, it confirms the potential of our unique patented drug delivery technology XR-17 – a novel derivative of vitamin A that we will be using in clinical trials with our other compounds for a number of human and veterinary indications. This also improves the possibilities to secure the company’s long-term financing.”

“Until now, veterinarians in the United States have not been able to safely use one of the most proven and commonly used chemotherapy agents used to treat human cancer. With the conditional approval of Paccal Vet-CA1, there is new hope for our canine patients,” said Dr. Chand Khanna, DVM, PhD, DACVIM, at The Oncology Service, LLC in Washington D.C., and past president of the American College of Veterinary Internal Medicine (Oncology). “Paccal Vet-CA1 is specifically formulated for use in dogs, giving us an important new weapon in the fight against canine skin and mammary cancers, which are both significant clinical problems in veterinary

oncology. I am enthusiastic about this new option and expect to use it widely for pets with these types of cancer."

"Pets are living longer and owners increasingly desire a 'human level of care' for serious and chronic conditions," said Andrea Wainer, divisional vice president and general manager, Animal Health, Abbott. "With the FDA conditional approval of Paccal Vet-CA1, we are able to offer veterinarians and pet owners a trusted cancer therapy used to treat millions of people each year."

Cancer accounts for nearly 50 percent of all deaths in dogs 10 years of age or older. It is the leading cause of canine disease-related deaths, with up to three million new cases diagnosed annually worldwide.

Canine squamous cell carcinoma, a type of skin cancer, is a malignant tumor of epidermal cells which is often developed in the oral and nasal cavities and on the paws. Light-skinned and short-haired dogs that spend a long time in the sunshine have a higher risk of squamous cell carcinoma.

Mammary carcinoma is the most common tumor in female dogs that have not been spayed, affecting one out of every four. Overweight females and those fed a diet high in fat are at the greatest risk for developing mammary cancer.

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Notes to editors:

About Paccal Vet®-CA1 (paclitaxel for injection)
Paccal Vet-CA1 is a paclitaxel cancer treatment developed especially for dogs. It is a novel formulation containing paclitaxel, one of the most frequently used human chemotherapeutic agents. Paccal Vet-CA1 is a novel nanoparticle formulation composed of Oasmia Pharmaceutical's patented excipient XR-17 that can be used to improve the solubility of substances like paclitaxel in suitable aqueous solvents. Two prospective, blinded, randomized trials to obtain full regulatory approvals in the U.S. and Europe are soon to be initiated.

In the United States, Paccal Vet-CA1 is indicated for the treatment of resectable and non-resectable squamous cell carcinoma (a type of skin cancer) in dogs that have not received previous chemotherapy or radiotherapy, and for the treatment of non-resectable stage III, IV or V

mammary carcinoma (mammary cancer) in dogs that have not received previous chemotherapy or radiotherapy. These indications are conditionally approved pending a full demonstration of effectiveness.

Paccal Vet (paclitaxel for injection) Important Risk Information

Contraindications, warnings and precautions: Do not use in dogs that have neutropenia (< 2000 cells/µL) or that have concurrent serious infection or in dogs that are pregnant, lactating or intended for breeding. Extravasation during administration can cause focal tissue necrosis and should be avoided. Persons sensitive to retinoids should avoid contact with the drug. Hospital staff and clients should use standard measures for handling cytotoxic drugs and should avoid contact with the drug and the patient's excretions for the recommended time period. The client should be educated in safe handling of their treated dog's excretions. More detailed preparation and administration information including special instructions for avoiding human exposure to waste products are supplied in the package insert and the client information sheet.

Adverse reactions: Paclitaxel can cause severe, transient bone marrow suppression within four to seven days of administration and can cause adverse gastrointestinal reactions due to transient gastrointestinal mucosal cell toxicity. In a field study, all the dogs treated (n=168) experienced at least one adverse reaction. Paclitaxel has a low margin of safety, but adverse reactions were manageable with appropriate patient monitoring and supportive care. The most frequent adverse reactions were: neutropenia, vomiting, anorexia, diarrhea, and lethargy. Less frequent but still significant adverse reactions included: alopecia, dehydration, dermatitis, hepatopathy, edema, pyrexia, and lameness. Other, less frequent adverse reactions included: urine abnormality, pruritus, erythema, anemia, loss of body condition, cutaneous ulceration, thrombocytopenia, neoplasia, polydipsia, conjunctivitis, and death and euthanasia.

See package insert for full prescribing information.

This is not a complete list of the Important Safety Information for Paccal Vet-CA1. For additional important safety information, please click for the Full Prescribing Information.

About conditional approval

A conditionally approved drug may be marketed for up to five years, subject to annual renewals, while collecting substantial evidence of effectiveness. Because full effectiveness of a conditionally approved drug has yet to be demonstrated and only a reasonable expectation of effectiveness has been

demonstrated for the specific indication(s), use of the drug in an extra-label manner is not allowed. Veterinarians can only use the drug for its approved indication(s).

In contrast, a fully-approved drug has already demonstrated substantial evidence of effectiveness and safety prior to marketing; therefore, there are no limitations on marketing and under certain conditions, a fully approved drug may be used in an extra-label manner.

About Oasmia Pharmaceutical AB
(NASDAQ OMX: OASM) (General Standard of Frankfurt Stock Exchange: OMAX, ISIN SE0000722365) Oasmia Pharmaceutical AB develops new generations of drugs within human and veterinary oncology. The company's product development aims to create and manufacture novel nanoparticle formulations and drug-delivery systems based on well-established cytostatics, which, in comparison with current alternatives, show improved properties, reduced side effects, and expanded applications. Oasmia's product development is based on its proprietary in-house research and company patents. The company's common stock is listed on NASDAQ OMX Stockholm and the Frankfurt Stock Exchange. www.oasmia.com