



2018-10-03

PRESS RELEASE

Oasmia Presents Positive Efficacy and Safety Data for Doxophos Vet in Treatment of Naïve Dogs with Lymphoma

Overall response rate data from the (RXE¹) Phase II study conducted in the US and Sweden met its primary end points and treatment with Doxophos Vet was generally well tolerated.

Oasmia’s assessment is that the positive safety and efficacy data will be sufficient for AdvaVet Inc. to seek conditional approval for Doxophos Vet in the US in the first half of 2019.

Uppsala, Sweden, October 3, 2018 – Oasmia Pharmaceutical AB (NASDAQ: OASM) today announce its analysis of the data from the Phase II study and it’s the follow-up has been finalized and summarized in a report. 17 dogs participated and were treated with Doxophos Vet in the main study and 8 of these continued in the follow-up part. The objective was obtained, 75% of the dogs with B-cell lymphoma showed a response after at least two treatment cycles. Progression free survival was defined as the time from screening to progression or death of any cause. The study results confirmed that the dose of Doxophos Vet defined in a prior dose-finding study is appropriate with regards to both efficacy and safety in dogs with lymphoma. The pharmacokinetic (PK) profile analyzed shows there is a rapid distribution of doxorubicin into the tissues, and that the Doxophos Vet formulation does not alter the release properties of doxorubicin when infused into the blood.

“The results of this Phase 2 study show that Doxophos Vet was well tolerated with substantial activity in canine lymphoma,” said Dr. Philip J. Bergman, DVM, MS, PhD, DACVIM-Oncology at the Katonah Bedford Veterinary Center, Bedford Hills, New York and a veterinary investigator on the trial.

Key efficacy results in the per protocol population from the Phase II study OAS-DOX-V02

Response type	Overall Response rate (ORR)		Progression Free survival (PFS)	
B-cell Lymphoma	n	9	n	16
	RR (%)	75.0	Median (days)	129
	95% CI	[42.8, 94.5]	95% CI	[41, 196]
			Min ; Max	28 ; 252

ORR is computed as (Sum of dogs with CR or PR after at least 2 treatments x 100)/Total number dogs receiving at least 2 treatments of Doxophos Vet.

The 95% confidence intervals are computed using the Clopper-Pearson exact method.

ORR of ≥ 75% in B-cell Lymphoma dogs establishes proof-of-concept with respect to the dose of Doxophos Vet used.

n = number of dogs with non-missing response data. CI = distribution free confidence interval of median.

¹ Study required for applying for Conditional Approval at FDA

The most frequently reported adverse reaction after Doxophos Vet treatment was myelosuppression. This is the most expected adverse reaction with chemotherapy. The majority of the adverse events, 88% in the main study and 69% in the follow-up were mild to moderate.

Julian Aleksov, Chairman of Oasmia Pharmaceutical commented that “The possibility to use Oasmia’s patented nano partical (< 100 nm size) based doxorubicin formulation represents a breakthrough, as no veterinary registered doxorubicin formulation is currently approved. We are convinced that this great news further strengthens and accelerates our commercial plans for AdvaVet Inc. to become the leading company within veterinary oncology”.

For more information:

Julian Aleksov, Executive Chairman

Tel: +46 18 50 54 40

E-mail: julian.aleksov@oasmia.com

Notes to editors:

About Lymphoma in dogs

Lymphoma is one of the most frequently diagnosed malignancies in dog and is the most commonly managed neoplasia in veterinary medical oncology. Lymphoma stems from the white blood cells that help the immune system to fight off infections. Lymphoma tends to affect the organs that play a role in the immune system but can occur in any organ. Lymphoma originates in from the lymphocyte cells of the immune system and involve neoplastic proliferation of T or B, or non-B/non-T type lymphocytes, occurring primarily in the bone marrow, lymph nodes, and visceral organs. Lymphoma with B-lymphocytes origin are the most common lymphoma in dogs. Given the systemic nature of canine lymphoma, chemotherapy is considered the therapy of choice.

About Doxophos Vet

Doxophos Vet is a patented nanoparticular formulation of the active substance doxorubicin and Oasmia’s excipient technology XR17 that the company is developing for the treatment of lymphoma, the most common cancer in dogs. The US Food and Drug Administration (FDA) has granted Oasmia MUMS Designation (Minor Use/Minor Species) for Doxophos Vet for the indication lymphoma, meaning the Company can apply for Conditional Approval to receive a quicker processing before launch. The distribution rights for Doxophos Vet are owned by AdvaVet.

About AdvaVet Inc.

AdvaVet is a U.S. based entity which holds all rights for Oasmia Pharmaceutical’s veterinary assets. AdvaVet is currently a fully owned subsidiary of Oasmia Pharmaceutical. Oasmia will present its long term vision and plan for AdvaVet during the fourth quarter 2018. To learn more about the Company, please [visit the website](#) or follow it on [Twitter](#) and [Facebook](#).

About Oasmia Pharmaceutical AB

Oasmia Pharmaceutical AB develops, manufactures, markets and sells new generations of drugs in the field of 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. The company's product development is based on its proprietary in-house research and company patents. Oasmia is listed on NASDAQ Capital Markets (OASM.US), Frankfurt Stock Exchange (OMAX.GR, ISIN SE0000722365) and NASDAQ Stockholm (OASM.ST).

Information is also available at www.oasmia.com www.nasdaqomxnordic.com www.boerse-frankfurt.de twitter.com/oasmia

This information is information that Oasmia Pharmaceutical AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 08.00 CET on October 3, 2018.