



PRESS RELEASE

FDA grants Oasmia MUMS designation for Doxophos® Vet

Oasmia Pharmaceutical AB, Uppsala, Sweden, has received Minor Use designation (MUMS) for Doxophos® Vet on the indication lymphoma. MUMS allows for a seven year market exclusivity when registered and eligibility for conditional market authorization.

Doxophos® Vet, Oasmia's investigational product to treat cancer in dogs, has received designation for Minor Use for the treatment of lymphoma 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 Doxophos® Vet before collecting all necessary efficacy data, but after proving the drug is safe. Conditional approval would allow Oasmia to market Doxophos® 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 status¹ for animal drugs is similar to Orphan Drug status for human drugs. This designation applies to the indication lymphoma. FDA made their decision after assessing the data which Oasmia previously submitted concerning the scientific rationale and development plan for the product candidate.

- This is very important information for Oasmia. It gives us the opportunity to apply for a conditional approval for Doxophos® Vet and the candidate may in this way generate revenue at a much earlier time, says Julian Aleksov, CEO of Oasmia.

About Doxophos® Vet

The active substance in Doxophos® Vet is doxorubicin, one of the most used cytotoxic substances in the world. Doxophos® Vet is currently in a Phase I trial to investigate the maximum tolerable dose.

About lymphoma

Lymphoma is a cancer disease where white blood cells are turned into tumors. Common lymphoma symptoms include severe anemia, severe fatigue, diarrhea, unnaturally high thirst, balance disruptions, eye changes, certain heart problems, etc. The disease is treated with cytostatics, in most cases Adriamycin™ (doxorubicin).

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

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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[&]quot;Oasmia is required under the Financial Instruments Trading Act to make the information in this press release public. The information was submitted for publication at 9.00 a.m. CET on July 4."