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PRESS RELEASE

Preliminary analysis indicates that Oasmia's product candidate Paccal® Vet met primary endpoint in Phase III study in dogs with mastocytoma

Oasmia Pharmaceutical AB announced today the preliminary results from a clinical Phase III study of dogs affected by mastocytoma (mast cell tumours), a type of skin cancer. The study measured the effect of Paccal® Vet. Preliminary analysis of data supports the primary endpoint that clinical response of dogs treated with Paccal Vet was superior to the active control lomustine and that the frequency of side effects was comparable between the groups. As expected, Paccal Vet resulted in less liver dysfunctions than in the lomustine group.

This is very positive news because of limited treatment options currently available for aggressive mastocytoma. A majority of dogs affected by aggressive mastocytoma rarely survives more than 6 months. The human registered anti-cancer drug lomustine has earlier been reported to have efficacy towards canine mastocytoma and is currently used in veterinary practice. Oasmia hence anticipates that Paccal Vet has the possibility to become a treatment option for dogs affected by mastocytoma. Currently there is no registered drug on the veterinary market with the active substance paclitaxel. Paclitaxel is a substance that is currently registered for a wide number of cancer indications in human oncology and is today the most prescribed oncology product. The use of paclitaxel in dogs has been limited, due to unacceptable side-effects from a fat soluble formulation. Oasmia's formulation of paclitaxel is based on their novel nanoparticulate formulation XR-17, which makes paclitaxel water soluble and therefore avoids the side effects with conventional paclitaxel. Oasmia intends to submit the data to the EMA and FDA for review.

- This is very exciting news for us in the veterinary oncology community. It would be very interesting if we were able to work with such a unique product as Paccal Vet, says Henrik von Euler, associate professor in veterinary oncology at the Swedish University of Agricultural Sciences, Sweden.

- This is an important milestone for Oasmia's Animal Health division. We are looking forward to the next step in this process, says Julian Aleksov, CEO at Oasmia.

About the phase III study

A multicenter, randomized, observer blind, controlled, Phase III study with stratified parallel group design. Patients were stratified according to tumour grade (II and III) and stage (IIa and IIIa). 249 patients who suffered from a measurable disease of mast cell tumour, grade II or III, and in whom surgery could not be performed, were treated in the study. The study measured the efficacy and safety of the test drug Paccal Vet compared with the control drug lomustine. The drugs were administered over 4 cycles in total with a follow-up period of 35 days following the last treatment.

About mastocytoma (skin cancer)

Mastocytoma is a cancer disease that originates from the mast cells, which are part of the body's immune system. Mastocytoma can occur in both sexes, in all ages and breeds of dogs. Mastocytoma exists as a systemic disease in which it affects the entire body and as a cutaneous disease in which it is located in the skin. The cutaneous is the most common form in dogs and constitutes approximately 20 % of tumours in the skin. The prognosis (meaning the prediction of the outcome of the disease) of dogs affected by mastocytoma depends upon a range of factors, of which two are size and location of the tumour. However, the most important factor is the grade. Low-grade tumours are more easily cured whereas no effective treatment is at present available for dogs with high-grade tumours. These tumours are aggressive and can potentially spread to distant parts of the body, leading to death for majority of these dogs.

About treatment of mastocytoma

The primarily treatment option at present for dogs affected by mastocytoma is surgery. However, successful surgical removal requires a small tumour that is located in an area of the body that can be removed without causing extensive dysfunction. The border between healthy and tumour tissue is not always clear and in order to avoid relapse, a wide margin of 2-3 centimetres surrounding the tumour needs to be removed as well. If the tumour is located on the leg, this margin might not be achieved without amputation. Local radiation therapy is an option if complete surgical removal is not possible. However, radiation therapy is not always applicable as the tumour cannot be located close to vital organs, the risk for side effects is high and not all tumours respond to radiation therapy. Finally, the poor availability of veterinary radiation therapy is currently a concern. Another treatment option is chemotherapy (anti-cancer drug). Currently, there is no registered drug on the veterinary market that targets all types of mastocytomas.

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. Paclitaxel is 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.

About Oasmia

Oasmia Pharmaceutical AB develops second and third generation cancer drugs based on nanotechnology for human and veterinary use. The broad portfolio is focused on oncology and contains several promising products in clinical and pre-clinical phase. Oasmia cooperates with leading universities and other biotech companies to discover and optimize substances with a favorable safety profile and better efficacy. The company name was registered in 1999 and is based in Uppsala, Sweden.