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PRESS RELEASE
OCTOBER 29 2018

Panion's meetings with US-FDA and the preferred US investigator clinic

Panion Animal Health AB develops an innovative treatment for epilepsy in dogs and targets the American market first. On the 22nd of October 2018, Panion held a pre-submission conference with the US-FDA in Washington DC, where the development product was presented for authority reviewers from both the FDA's Center for Veterinary Medicine (CVM) and other authority centers. Panion had five persons involved in the meeting; regulatory FDA-expert Dave Petrick, Director of Business Development Carlos N. Velez, and CEO Anja Holm, who were supported by two of Panion's scientific experts over the telephone.

"The dialogue was open, interested and curious, and the central reviewers from FDA-CVM came across very well prepared and helpful" says Anja Holm. *"We had prepared well for this meeting, using both documents and pre-meetings with excellent assistance from our US-expert, Dave Petrick."*

In the meeting, Panion explained the technology, the status of development, the plans for development of the product, and answered many questions from the authorities. The FDA reviewers raised a number of clarifying questions that will need in-depth consideration and documentation. On several important issues, firm clarifications and good advice were provided, which will help Panion forward.

"It is my impression that FDA is very willing to guide us along the way. They expressed several times the opportunity for intermediate exchanges and comments, and for protocol concurrence prior to starting pivotal studies, to ensure acceptability of the data from such studies, when we submit the data package" says Anja Holm.

Ready for the presubmission conference at FDA-CVM; Anja Holm, Carlos Velez.

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Developing animal health – In Panion, we want to improve the quality of life for animals suffering from chronic diseases. We are convinced that gene therapy has promising prospects. Our aim is to develop and commercialize a gene therapy treatment for dogs with drug refractory epilepsy, based on CombiGene AB's technology and platform. Panion Animal Health AB is listed at Spotlight Stock Market.

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"Clearly, they acknowledged the need for a tailored approach to this gene therapy treatment, because there are no guidelines that fit completely. This was extremely important to us, so we will not be confined by rigid rules created for ordinary chemical-pharmaceutical products. And it was great to see how our enthusiasm for this new technology opened for curious questions and discussions on future manufacture, use, and application."

Panion is also progressing the next step in the development plan after the recently finalized safety study in dogs; a pilot study in family dogs with true drug-refractory epilepsy. In the days following the FDA-meeting, Panion held meetings at the preferred investigator clinic, with the central staff members and coordinators, the veterinary neurologists, and with an American lawyer to ensure that all precautions are respected. Panion's clinical trial monitor, Beth Oman, provided valuable input to the practical conduct of the study, roles, responsibilities, and potential pitfalls to avoid. Carlos Velez and Anja Holm provided sparring to the neurologists on the technological background, study plans, and timelines.

The complex coordination of technique, schedule of events for enrolled dog patients, strict protocol compliance, data capture, and data handling was discussed in detail with the very professional and experienced staff. The necessary changes will be introduced in the drafted plan and as soon as everything is settled, we will announce the study start.

"I am very optimistic after this trip" says Anja Holm. *"The level of professionalism, flexibility, and helpfulness was overwhelming, both from the officials in FDA and the experts and staff at the investigator site. The potential of this gene therapy for the unmet medical need seems clear to all and they were curious to learn more about the innovative approach to treatment of epileptic dogs".*

Ready for the presubmission conference at FDA-CVM; Dave Petrick.

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