

Panion prepares for USA

Panion Animal Health AB develops a novel treatment for epilepsy in dogs and targets the American market first. In week 43, 2018, Panion is invited to a meeting with the US-FDA in Washington DC where the development product will be presented for authority reviewers from both FDA and USDA. From Panion, three persons will participate in person; regulatory FDA-expert Dave Petrick, Director of Business development Carlos N. Velez, and CEO, DVM Anja Holm. In addition, the FDA project manager has accepted to establish a telephone connection to two of Panion's scientific experts, so they can listen in and answer specific questions.

"We are really excited that this important meeting is taking place now. A presubmission meeting with the authorities, who will evaluate the application in the end, is of utmost importance. We have prepared and submitted a long document to the FDA including a list of questions that we expect to get the reviewers feed-back on. This will help us make the development plan as concrete as possible, including getting a firm estimate of the development costs and timelines." says Anja Holm.

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 same week, meetings will be held at the investigator clinic, which is an optimal choice of clinic because of its large size, full equipment, and the highly skilled staff, including veterinary neurosurgeons and neurologists. The meetings will concern details of the study plan, roles, responsibilities and timelines.



"The expert neurologists at the clinic are very interested in our innovative treatment for this group of dogs that are currently lacking good treatment options, and they seem optimistic with regards to the speed of enrollment in the study, which is very encouraging for us. We aim at good progress in the pilot-study and expect to send out further details when we are back from the tour" says Anja Holm.

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Panion Animal Health AB

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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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