

Panion starts clinical study in dogs

Panion Animal Health AB develops a novel gene therapy treatment for dogs with epilepsy. The first clinical trial will be conducted at Long Island Veterinary Specialists, Ophthalmology, Surgery, Internal Medicine, Emergency, PLLC ("LIVS") in New York, USA. It is a pilot study to evaluate the efficacy of the treatment in patient dogs with idiopathic epilepsy. It is the first time that the gene therapy treatment is made available for client-owned family dogs.

The study activities will start immediately, and the first dog-patient is expected to be enrolled in Q1-19. Depending on the speed of enrollment and other study related factors, we expect to have preliminary results in the end of Q4-19.

"This is a major step in Panion's development plan for our product for dogs suffering from epilepsy. I am very happy to be able to make this announcement after many months of hard work. The agreement with LIVS is signed and we are in the best professional hands with LIVS's top-class neurologists in a highly competent veterinary hospital. We are many who have pushed impatiently for this announcement, but we have had to accept the rule of the three T's; Things Take Time" says Anja Holm, CEO of Panion.

The pilot study follows the successful safety study in dogs conducted earlier in 2018 in cooperation with the University of Copenhagen. The final study report is pending but the most important preliminary results have been released, showing that dogs tolerate the gene therapy very well.

Provided a good outcome of the pilot study, Panion must conduct a regulatory safety study in experimental dogs after protocol concurrence from the US-FDA Center for Veterinary Medicines. For this study, the gene-vector should be produced under the quality assurance system Good Manufacturing Practice (GMP) in order to conform to the guidelines recommended by regulatory agencies for veterinary medicines.

The manufacturing development for Panion's epilepsy product is governed by the license agreement with CombiGene and timelines therefore depend on CombiGene's progress in the GMP production. Earlier this year, CombiGene secured financing of the manufacturing development for the product (CG01).



Anja Holm, CEO, Panion Animal Health

This press release contains information which Panion Animal Health AB is obliged to publish according to the EU market abuse regulation (MAR). This information was submitted by Panion's CEO, Anja E. H. Holm, for publication on December 12 2018.

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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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