

## **Panion's epilepsy product candidate for gene therapy in the dog: FDA has established an Investigational New Animal Drug (INAD) file.**

Panion Animal Health AB ("Panion") has in Q4-17 requested the FDA to open an Investigational New Animal Drug application file to carry out the development of our new product for use in the dog. Panion plans to develop and gain approval for the use of CG-01-canine, a recombinant adeno-associated virus vector expressing neuropeptide Y and receptor peptide Y2 to treat drug refractory idiopathic epilepsy in the dog via intracranial injection.

A summary of the scientific rationale for the therapy and the preliminary work completed to date was submitted and the FDA accepted this with a response letter, which was received from our US consultant on January 02, 2018. Because a MUMS status for Panion development product has been granted, in which the Sponsor User Fee was waived, the application is free of charge for Panion.

The opening of the INAD means that Panion may request a meeting with the FDA and propose a detailed plan of development for discussion with the authorities. In addition, the INAD is prerequisite for shipping of the investigational drug product to the clinical trial investigators in US.

*"It is great to see that we are making progress in these regulatory areas, because this is the pathway to authorization of a product"* says Anja Holm, CEO of Panion.

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 January 03 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 AktieTorget.

### **Panion Animal Health AB**

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