PANION™
DEVELOPING ANIMAL HEALTH

PRESS RELEASE
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FDA grants MUMS status and sponsor fee waiver to Panion's epilepsy project.

After a review of the request and documentation submitted by Panion in June 2017, the FDA has decided to grant the MUMS status and a sponsor fee waiver to Panion's development product for treatment of drug-refractory idiopathic temporal-lobe epilepsy in dogs. FDA's decision is based on the so-called Minor Use in a Major Species – MUMS. The MUMS designation is a status similar to the Orphan Drug status for human drugs. The MUMS status gives no guarantee that the product will be approved in the end, but it entitles Panion to a 7-year period of exclusive marketing rights following approval, and it provides eligibility to apply for MUMS grants, which could help to advance the development. The fee waiver means that we do not have to pay the annual sponsor fee of approximately 75.000 US dollars to FDA.

"It is very reassuring that FDA grants the MUMS status, and the connected fee waiver opens the door to the INAD application for Panion's epilepsy product for dogs" 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 September 18 2017.

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In June 2015 CombiGene formed a wholly owned subsidiary, then called CombiGene Vet AB, and in April 2016 the decision was taken to distribute the subsidiary to CombiGene's shareholders with the aim of listing the company. The company, which has been renamed Panion Animal Health AB, will use CombiGene's discoveries to develop a treatment for canine epilepsy. Panion aims at inlicensing or acquiring other veterinary medicine projects or products.

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