PANION™
DEVELOPING ANIMAL HEALTH

PRESS RELEASE
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Fee waiver 2019

The company has re-applied for a fee waiver for 2019 and received positive answer from US-FDA again, as for fiscal years 2017 and 2018. This means that also for 2019, the company must not pay the very high fee for a running application to the FDA. The fee waiver is granted as a result of the MUMS determination (Minor Use Minor Species) for the product.

Categorical exclusion for environmental assessment

Panion has also applied to US-FDA for claiming a so-called "Categorical Exclusion" (CE) under 21 CFR 25.33(e) for the investigational use of CG-01-canine with regards to environmental requirements for the clinical trials to be conducted. This has been agreed by the FDA, and therefore neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required for the investigational use in clinical trials. This is a clear reduction of the regulatory and administrative burden for the company, because environmental assessments can be very comprehensive and labour intensive.

For additional information, contact:
Anja E. H. Holm, CEO | +45-22 94 66 00
anja.holm@panion-animalhealth.com

Panion Animal Health AB
info@panion-animalhealth.com

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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