Vantia Therapeutics Initiates the EQUINOC® Study, a Pivotal Study with Fedovapagon for the Treatment of Nocturia in Men with Benign Prostatic Hyperplasia

Southampton, UK, 22 March 2016 – Vantia Therapeutics announces it has initiated the EQUINOC® Study, pivotal clinical study to investigate the efficacy and safety of fedovapagon (VA106483) in the treatment of nocturia in men with benign prostatic hyperplasia (BPH) (the "EQUINOC" study).

Nocturia is a common condition that causes sufferers to wake frequently during the night in order to urinate ("nocturnal or night-time voids"). Its prevalence and severity increases markedly with age and it is often the presenting symptom in men with BPH (enlarged prostate gland), affecting at least 70% of BPH patients. Nocturia has a significant detrimental impact on the quality of life in patients. Current treatment options are limited for a market estimated at more than US$1 billion.

Fedovapagon is a selective, small molecule vasopressin V2 receptor agonist, discovered by Vantia scientists, that has an anti-diuretic effect through stimulation of V2 receptors in the kidney. Preliminary efficacy and safety of fedovapagon, and a dose for the EQUINOC trial, has been established in several completed clinical studies.

EQUINOC is a randomised, double-blind, placebo-controlled, multi-centre study aiming to enrol approximately 400 patients in the US with preliminary results and analysis expected in the third quarter of 2017. Patients will be randomised to receive fedovapagon or placebo each evening over a 12-week treatment period. The co-primary efficacy endpoints are reduction in the mean number of night-time voids (waking and urinating) and change in the NocTIMe®, a patient reported outcome score. Vantia developed the NocTIMe® specifically to assess the effect of treatment on the quality of life of nocturia patients.

Dr Marc Gittelman of South Florida Medical Research and Chief Investigator of the trial, added: "Nocturia has a significant detrimental effect to the quality of life of a large number of patients. Waking multiple times each night to void negatively impacts the quality of sleep and how patients feel and function during the day. Despite this significant problem, there are no approved drug treatments for nocturia in the United States. The results of clinical studies with fedovapagon to date provide a strong indication of its potential to reduce nocturnal urine production in men with BPH. These findings provide an excellent basis on which to undertake a pivotal registration trial to advance this novel treatment."

Martin Edwards, Chairman of Vantia, said: "Results from our clinical programme with fedovapagon to date clearly highlight its potential as a novel treatment for nocturia in men with BPH. Strong financial support from our investors will enable us to conduct this well-designed and robust pivotal clinical trial, which is now underway and has a made a strong start to patient enrolment. We look forward to the preliminary results in the third quarter of 2017."

Fedovapagon clinical results to date

Phase II studies conducted by Vantia with fedovapagonin nocturia patients demonstrate its safety and efficacy, and identified a dose for the pivotal EQUINOC trial.

Key findings from a Phase II study in BPH patients were that patients showed a statistically significant reduction in mean nocturnal urine volume and void frequency across a range of doses of fedovapagon compared to placebo.

Key findings in a Phase IIb study were:

- Patients receiving a 2mg dose of fedovapagon had a clinically meaningful reduction in nocturnal void frequency between the baseline period and the end of a 12-week treatment period and the change was larger than in the placebo group (p=0.036).
- Fedovapagon was well tolerated in patients, with no treatment-related serious adverse events reported, and importantly no difference in the effect on serum sodium levels between the treatment and placebo groups. Hyponatraemia is a documented adverse event commonly reported with other vasopressin agonists used to treat nocturia.

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About Vantia Therapeutics:
Vantia Therapeutics is an emerging pharmaceutical company developing novel, small molecule drugs targeting large areas of unmet medical need. Its lead clinical candidate, fedovapagon (VA106483), was discovered by Vantia scientists and is in a pivotal clinical study for the treatment of nocturia in men with benign prostatic hyperplasia (BPH). The Company was founded in 2008 and is backed by specialist life science investors Novo A/S, SV Life Sciences and MVM Life Science Partners.
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