Vantia Therapeutics announces Positive Results from its Phase III EQUINOC® Study, a Pivotal Trial with Fedovapagon for the Treatment of Nocturia in Men with Benign Prostatic Hyperplasia

Southampton, UK, 3 October 2017 – Vantia Therapeutics announces positive top-line data from a pivotal Phase III trial investigating the efficacy and safety of fedovapagon (VA106483) in the treatment of nocturia in men with benign prostatic hyperplasia (BPH) (the "EQUINOC" study).

The EQUINOC trial is a 432-patient randomised, double-blind, placebo-controlled, multi-centre study conducted in the US. Patients were randomised to receive fedovapagon or placebo orally each evening over a 12-week treatment period.

The trial met both its co-primary endpoints, demonstrating a reduction in nocturnal voids (waking and urinating: $p<0.001$) and improved quality of life through a patient reported outcome score, NocTIMe® ($p=0.034$). The clinical significance of treatment was supported by statistically significant results for other endpoints including time to first void ($p<0.001$), nights when patients have 0 or 1 voids ($p<0.006$) and patients who reduce their voids by 50% ($p<0.001$).

Fedovapagon was generally well tolerated which, in combination with the efficacy endpoints, strengthens the potential for it to be a safe and effective treatment for nocturia in men with BPH. A second pivotal Phase III study based on the same endpoints and population will now be conducted with the goal of providing further data required to support regulatory filings for marketing approval in the US and Europe.

Further results and analysis from the EQUINOC trial will be presented at upcoming scientific meetings.

Marc Gittelman, CEO and Director of South Florida Medical Research and Principal Investigator of the EQUINOC study, commented: "This positive top-line Phase III data marks extremely important progress made in the development of fedovapagon for the treatment of nocturia in men with BPH. There are currently no marketed drug treatments for nocturia in the US, despite its significant detrimental effect to the quality of life of a large number of patients. The positive results we have seen suggests that fedovapagon could offer an important new treatment option to nocturia sufferers."

Andrew Crockett, Director of Vantia, added: "We are delighted with the positive outcome of this first Phase 3 trial with fedovapagon. We are also very encouraged by FDA's recent first drug approval for nocturia and look forward to conducting a second pivotal study to confirm the data from the EQUINOC study and ultimately support a marketing approval."

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$2 billion.

Fedovapagon is selective, small molecule, oral vasopressin V2 receptor agonist, discovered by Vantia scientists, that has an anti-diuretic effect through stimulation of V2 receptors in the kidney.

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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 has produced positive Phase III results from the EQUINOC® Study for the treatment of nocturia in men with benign prostatic hyperplasia (BPH). A second study will now be conducted with the aim of filing for marketing approval in the US and Europe, pending a successful outcome. Vantia was founded in 2008 and is backed by specialist life science investors Novo Holdings A/S, SV Health Investors and MVM Life Science Partners.
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