

## **Vantia Therapeutics' VA111913 Enters Phase II Proof-of-Concept Trials for Dysmenorrhoea**

### **Phase I results show VA111913 to be safe and well tolerated**

**Southampton, UK, 6 October 2009** – Vantia Therapeutics today announces that its novel oral small molecule drug for the treatment of dysmenorrhoea (painful menstruation) has entered Phase II proof-of-concept trials. In addition, Vantia announces results of the successful Phase I trial of VA111913, which showed the product candidate to be safe and well tolerated.

The Phase II Proof of Concept study is a multi-centre, double-blind, placebo-controlled trial being conducted at sites in the UK and the US. The trial will recruit 128 women aged between 18 and 35 years with primary dysmenorrhoea including a consistent history of menstrual pain that limits daily activity and typically requires medication for relief. Subjects will be dosed with VA111913 and placebo in a cross over design during consecutive menstrual cycles. They will be dosed for up to a maximum of six days, beginning two days before the onset of menstruation. Subjects will then assess the menstrual pain, bleeding and amount of analgesia required to treat symptoms during each cycle. Results are expected in H2 2010. Further details of the trial and of study site locations can be found on the website [www.clinicaltrial.gov](http://www.clinicaltrial.gov).

Dr Jim Phillips, CEO of Vantia Therapeutics, said, "Dysmenorrhoea affects a large number of women and there is currently no targeted therapy to treat the condition. VA111913 has been shown to normalise the contraction of smooth muscle and thus has the potential to directly target the cause of dysmenorrhoea by acting on the smooth muscle in the uterus wall. We believe this could offer an effective alternative to over-the-counter painkillers and 'off label' use of contraceptive drugs. The rapid progress of VA111913 underlines the quality of product candidates generated by our small molecule drug discovery capabilities and the ability of our team to drive them towards commercialisation."

The First-in-Human Phase I study comprised a single ascending dose phase, multiple ascending dose phase and a food effect study. Study treatment was generally well tolerated; all adverse events reported by subjects on active VA111913 treatment were mild and transient. No serious adverse events were reported during the study and no subject was withdrawn from the study due to an adverse event. There was no apparent dose-dependent effect on the nature or severity of adverse

events reported. The pharmacokinetic profile of the product is supportive of twice daily dosing.

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**Notes to Editors:**

**About Vantia Therapeutics:**

Vantia Therapeutics is an emerging pharmaceutical company developing novel, small molecule drugs targeting large, underserved medical markets. Its rapidly advancing clinical pipeline includes VA106483 for nocturia in BPH patients and VA111913 for dysmenorrhoea, product candidates which directly target conditions that together affect many millions of people, are poorly treated and represent billion dollar markets. Vantia was spun out from Ferring Research Ltd in 2008 and its pipeline is driven by the proven small molecule drug discovery and development capabilities of that unit and Vantia's experienced management team. Vantia's strategy is to develop candidates to Phase II proof-of-concept and then commercialise through partnerships. The Company is well-funded and backed by specialist life science investors MVM Life Science Partners, SV Life Sciences and Novo A/S.

[www.vantiatherapeutics.com](http://www.vantiatherapeutics.com).

**About VA111913 and dysmenorrhoea:**

VA111913 is an oral small molecule drug candidate in Phase II clinical development for prevention and treatment of dysmenorrhoea, a condition characterized by abnormal contractions of the uterus during menstruation causing severe pain. Dysmenorrhoea is associated with raised vasopressin levels. VA111913 acts by blocking vasopressin 1a receptors in smooth muscle in the uterus wall. VA111913 has been demonstrated in preclinical trials to normalise smooth muscle contraction in response to vasopressin, thereby offering the potential for it to be the first drug that directly targets the cause of this condition in the uterus.

A Phase I trial with VA111913 has been completed and a Phase II proof of concept study is currently underway. This is due to complete by H2 2010.

Dysmenorrhoea affects a large number of women for whom there are currently no targeted therapies; treatments that are in common use however include over-the-counter painkillers (e.g. naproxen or ibuprofen) or oral contraceptives used 'off-label'. It is estimated that the market opportunity for a targeted drug for the prophylaxis and treatment of dysmenorrhoea is at least \$1 billion per year.