KaNDy Therapeutics announces positive clinical data with lead candidate NT-814 for the treatment of symptoms of the menopause

"Phase Ib/IIa data showed rapid and highly significant reductions in the frequency and severity of hot flashes and the number of night time awakenings~

"NT-814 is being developed to provide a valid alternative to hormone replacement therapy and will now move into a Phase Ib trial~

"KaNDy Therapeutics also announces it will be attending the 16th World Congress on Menopause in Vancouver from 6-9 June~

Stevenage, UK, 7 June 2018 – KaNDy Therapeutics, a UK clinical-stage biotech company, today announces positive data from the Phase Ib/IIa clinical trial with its lead non-hormonal drug candidate, NT-814, for the treatment of symptoms of the menopause.

Results from the trial provide compelling evidence that NT-814, a novel, once-daily, oral neurokinin-1,3 receptor antagonist, produces a rapid and profound reduction in debilitating symptoms of the menopause including vasomotor symptoms (VMS), also known as HF, and night time awakenings.

Based on these results, KaNDy Therapeutics intends to advance NT-814 into a fully powered Phase Ib definitive dose-ranging study in patients suffering from debilitating symptoms of the menopause. The Phase Ib trial will begin later this year.

The Phase Ib/IIa RELENT-1 study was a randomised, double-blind, placebo-controlled study conducted at three clinical pharmacology units (CPU s) in the US. Seventy-six women aged 41 to 64 years experiencing 7-20 moderate or severe hot flashes/flushes (HF) per week were recruited into the study and randomized to receive one of four escalating doses of NT-814 or placebo.

Treatment with NT-814 once daily for two weeks at the most effective dose evaluated, resulted in rapid and highly significant reductions in:

- the **frequency** of HF, with a reduction of 62% from baseline in the number of moderate and severe HF vs 24% for placebo in Week 1 (p<0.0014) and an 84% reduction from baseline vs 37% for placebo in week 2 (p<0.0002)
- the **severity** of HF, with a reduction of 23% from baseline in average HF severity vs 9% for placebo in week 1 (p<0.015) and a 50% reduction from baseline vs 16% for placebo in Week 2 (p<0.0004)
- the number of **night time awakenings**, with a reduction of 58% from baseline vs 17% for placebo in Week 1 (p< 0.0022) and an 81% reduction from baseline vs 32% for placebo in Week 2 (p< 0.0005).

NT-814 was well tolerated with no safety concerns across the dose range including routine safety labs, liver function tests, ECGs and vital signs.
Professor Richard Anderson, Elsie Inglis Professor of Clinical Reproductive Science, University of Edinburgh, and a scientific and clinical advisor to KaNDy Therapeutics, said: “These are very promising results which suggest that NT-814, a novel once daily treatment taken orally, may offer women with debilitating symptoms of the menopause, a real alternative to hormone replacement therapy (HRT). In contrast to HRT, which can take weeks or months to be fully effective, both hot flashes and night-time awakenings responded rapidly and with big changes with NT-814.”

In addition, KaNDy Therapeutics announces it will be attending the 16th World congress on Menopause taking place in Vancouver, Canada, from 6-9 June 2018. To arrange a meeting with Dr Mary Kerr, Managing Director of KaNDy Therapeutics at the congress, please contact info@kandytherapeutics.com

About the RELENT-1 Study: The Phase Ib/Ia RELENT-1 study was a randomised, double-blind, placebo-controlled study conducted at three clinical pharmacology units (CPU) in the US. Seventy-six women aged 41 to 64 years experiencing 7-20 moderate or severe HF s per week were recruited into the study and randomized to receive one of four escalating doses of NT-814 or placebo in four cohorts. Study drug was taken once daily in the morning for 14 days, the first seven of which were resident in the CPU. Subjects completed diaries twice daily for the two weeks before and throughout treatment and underwent routine safety assessments periodically throughout the trial. Further information on the study design can be found on www.clinicaltrials.gov and full results of the study will be published at scientific congresses and in peer-reviewed journals over the coming months.

NT-814 is an orally administered, potent and selective small molecule dual antagonist of both the neurokinin-1 and 3 receptors under development by KaNDy as a therapy for a range of Women’s Health conditions. NT-814 addresses VMS by modulating a group of oestrogen sensitive neurones in the hypothalamus in the brain (the KNDy neurones), that in menopausal women due to the absence of oestrogen, become hyperactive and consequently disrupt body heat control mechanisms resulting in the debilitating vasomotor symptoms of HF.

KaNDy Therapeutics is a clinical-stage company focused on optimizing the potential of NT-814 in the treatment of common, chronic debilitating female sex-hormone related conditions. These conditions, such as post-menopausal VMS, are debilitating for women often over many years and associated with significant healthcare and economic costs.

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