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KaNDy Therapeutics Announces Positive Phase 2b Data in Post-Menopausal Women with its Lead Non-Hormonal Product NT-814

~Phase 2b dose range finding study showed rapid and highly significant reductions in the frequency of hot flashes (primary endpoint) for the full 12-week treatment period~

~Reduction in hot flashes was associated with statistically significant improvements in quality of life, mood and sleep – all key secondary endpoints~

~ All doses of NT-814 were well tolerated during the study, demonstrating a safety profile that supports progression to Phase 3 ~

Stevenage, UK, 13 January 2020 – KaNDy Therapeutics, a UK clinical-stage biotech company, today announces positive data from the Phase 2b "SWITCH-1" clinical trial with its lead non-hormonal drug candidate, NT-814, for the treatment of symptoms of the menopause.

Following on from the clear benefits NT-814 demonstrated in the Phase 2a RELENT-1 study, the SWITCH-1 trial provides further compelling evidence that NT-814, a first in class, once-daily, oral neurokinin-1,3 receptor antagonist, can produce a rapid and marked reduction in the most troublesome and frequent symptoms of the menopause, hot flashes and night sweats (vasomotor symptoms). The clinical relevance of the marked improvements shown on the vasomotor symptom endpoints was supported by highly statistically significant improvements across patient reported assessments of quality of life, mood and sleep.

The SWITCH-1 study was a randomised, double-blind, placebo-controlled trial conducted in the US, UK and Canada. One hundred and ninety-nine women experiencing at least 7 moderate or severe hot flashes/flushes (HF) per day were recruited into the study and randomised to receive one of four

doses of NT-814 or placebo. Treatment with NT-814 once daily for 12 weeks at the most effective dose evaluated resulted in:

- Statistically significant reductions compared to placebo in average **hot flash frequency** (primary endpoint), starting during the first week of treatment and continuing throughout the 12-week treatment period. Least squares mean reductions in average hot flash frequency were -6.7 for NT-814 vs -2.7 for placebo at week 4, and -7.8 vs -4.7 at Week 12 ($p<0.0001$ and $p=0.0092$, respectively).
- Marked improvements in all key secondary endpoints: improved **quality of life** was shown by highly significant improvements over placebo in the MenQoL menopause-specific quality of life scores, benefits on **mood** were demonstrated by significant improvements in the Beck Depression Inventory (II), and improved **quality of sleep** was shown by statistically significant improvements compared to placebo in the Pittsburgh Sleep Quality Index scores.
- NT-814 was well tolerated across the dose range with a safety profile that supports progression to Phase 3.

Dr. James A. Simon, Clinical Professor of Reproductive Endocrinology & Infertility at George Washington University, and the study's Lead Investigator, commented:

"*These top-line results of the SWITCH-1 study are very exciting. They demonstrate that NT-814, a truly novel therapy, offers a rapidly effective, non-hormonal approach to treating menopausal hot flashes and night sweats, debilitating symptoms of menopause. Unique to this trial, patients also reported improvements in quality of life, mood and sleep with NT-814.*"

Dr Mary Kerr, Co-Founder and CEO KaNDy Therapeutics, said:

"*The SWITCH-1 study started in November 2018, and so we are excited to share such positive results on schedule. The data confirms and validates Phase 2a observations, providing more evidence that neurokinins are fundamental to sex hormone biology and the pathophysiology of the menopause, resulting in almost immediate symptom relief. The Company looks forward to presenting these data at future scientific meetings and discussing it with regulatory agencies in advance of progressing the compound into pivotal registration studies.*"

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About the SWITCH-1 Study: The Phase 2b SWITCH-1 study was a randomised, double-blind, placebo-controlled study conducted at 25 sites in the UK, US and Canada. It included an adaptive randomisation design that enabled the randomisation ratio to be modified to focus on doses of greatest interest based on emerging data. The study was initiated in November 2018 and completed, ahead of schedule, at the end of 2019. A total of 199 post-menopausal women experiencing at least 7 moderate or severe HFs per week were recruited into the study and randomized to receive one of four doses of NT-814 or placebo. Study drug was taken once daily in the evening for 12 weeks. Subjects completed electronic diaries twice daily for the two weeks before and throughout treatment and underwent routine safety assessments periodically throughout the trial. Patient reported assessments of sleep, quality of life and mood were also completed periodically during study visits. 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 vasomotor symptoms 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 hot flashes and night sweats.

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 vasomotor symptoms, are debilitating for women often over many years and associated with significant healthcare and economic costs. NT-814 is wholly owned by KaNDy.