KaNDy Therapeutics announces initiation of Phase 2b trial of NT-814 for the treatment of troublesome post-menopausal symptoms

Stevenage, UK, 11 December 2018 - KaNDy Therapeutics, a clinical-stage company developing a potential breakthrough non-hormonal treatment for multiple debilitating symptoms of the menopause, today announces initiation of the Phase 2b clinical trial evaluating NT-814 in women with troublesome symptoms of the menopause. The study (called SWITCH-1) will evaluate the effect of treatment with NT-814 on hot flashes and other symptoms of the menopause.

Dr. Steve Pawsey, Chief Medical Officer of KaNDy Therapeutics, said: *"We are very pleased to have initiated the Phase 2b, SWITCH-1 study, on schedule with our previous guidance. We anticipate that results from this trial will validate the Phase 2a results and position NT-814 as a novel, non-hormonal treatment for women suffering from troublesome symptoms of the menopause. We will continue to enrol patients over the coming months and look forward to reporting results in late 2019. We expect NT-814 to be fully Phase 3 ready in H2 2020"*

Prof. James A. Simon, Coordinating Principal Investigator on the SWITCH-1 Study and Scientific and Clinical Advisor to KaNDy Therapeutics said: *"There are millions of women worldwide suffering from debilitating symptoms of the menopause and a non-hormonal treatment that could offer relief would be extremely valuable to this population. NT-814 has delivered very encouraging results to date and I am hopeful that findings from this trial will be equally promising."*

SWITCH-1 is a Phase 2b, double-blind, randomised, placebo-controlled, adaptive study designed to determine the effectiveness and safety of NT-814, taken once daily, for the treatment of troublesome post-menopausal symptoms. Four doses of NT-814 (40 mg once a day, 80 mg once a day, 120 mg once a day and 160 mg once a day) will be investigated and compared to placebo, in five parallel groups. The study is anticipated to enrol approximately 165 postmenopausal women aged 40 to 65 years although the exact number will be determined during the adaptive design reviews. Subjects will participate in the study for a total of approximately 19 weeks, comprising a screening period of three weeks, a 12-week treatment period and then a final follow up visit four weeks after the end of the treatment period. The co-primary efficacy endpoints will be the change from baseline in frequency and severity of moderate and severe hot flashes at Weeks 4 and 12 of treatment.

More information can be found at www.clinicaltrials.gov, identifier: NCT03596762

For more information, please contact:

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KaNDy Therapeutics is a clinical-stage company developing a potential breakthrough non-hormonal treatment for multiple debilitating symptoms of the menopause including hot flashes and sleep disturbance due to night sweats. KaNDy's drug in development, **NT-814** is a unique dual mechanism NK(neurokinin)-1,3 receptor antagonist with the potential to 'switch off' multiple debilitating symptoms of the menopause without the need for oestrogen exposure.

Data from a Phase 1b/2a study in post-menopausal women with troublesome hot flashes showed NT-814 was able to rapidly and profoundly reduce both the frequency and severity of hot flashes as well as sleep disturbances due to night sweats. NT-814, is now being evaluated in a Phase 2b clinical trial in postmenopausal women with moderate to severe vasomotor symptoms. Headline results are expected at the end of 2019 and NT-814 will be fully Phase 3 ready by H2 2020.

For more information please visit https://www.kandytherapeutics.com/