TauRx Therapeutics
Innovation in neurodegeneration

LUCIDITY Study – Protocol Amendment

ABERDEEN, Scotland and Singapore, 20th July, 2018 – TauRx Therapeutics Ltd has announced that it has revised the design of its LUCIDITY clinical study (Study TRx-237-039) in light of new guidance issued by the FDA ("Early Alzheimer's Disease: Developing Drugs for Treatment") and the European Medicines Agency ("Guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease") in February 2018. Both guidance documents recognise the importance of treating early stages of Alzheimer's disease (AD) and offer a clearer regulatory framework for conducting trials in Early AD.

The Company's Executive Chairman and Co-Founder, Prof. Claude Wischik, commented: "When we launched this study towards the end of 2017, it was intended as a relatively small 6-month imaging biomarker study with a single FDG-PET-based primary endpoint aiming to confirm the efficacy of LMTX® at the low dose of 4 mg twice a day, compared with placebo in patients with very mild AD not currently taking approved symptomatic treatments. While the new guidance documents welcome the potential role of biomarkers in trials in Early AD, they also emphasize the need to demonstrate meaningful clinical benefit in terms of cognition and function. We have therefore extended and enlarged the study to permit a clinical readout to be achieved over the shortest possible treatment period as a gated co-primary outcome, given that patients are required not to take cholinesterase inhibitors or memantine in combination with LMTX®. The brain imaging biomarker remains the primary outcome."

The key changes reflected in the revised study protocol are as follows:

a) The target patient population has been expanded to cover patients with Early AD, including patients having either Mild Cognitive Impairment or a very early stage of mild AD.

b) The treatment duration has been extended from 6 months to 9 months to give time for the potential benefits in cognition and function (previously seen at 9 months in patients taking the 4 mg twice a day dose of LMTX®) to be confirmed. These will be assessed using the most sensitive elements of the ADAS-cog and ADCS-ADL neuropsychological assessment scales combined into a single composite scale. The clinical outcome will be analysed as a gated co-primary that will depend on the biomarker achieving statistical significance first.

c) The number of subjects to be enrolled in the study has been increased to provide sufficient power to detect a clinical benefit over 9 months. There will now be 150 subjects receiving 4 mg of LMTX® twice a day and 150

subjects receiving placebo (previously 90 each). In addition, a further exploratory arm with 75 subjects has been added to see whether a somewhat higher dose of LMTX® (8mg twice a day) provides any additional benefit.

d) Patients will also now be required to have positive PET scan evidence indicating the presence of amyloid-β pathology before entering the study.

e) While the study remains open only to those patients not taking currently approved symptomatic treatments for AD, the screening period has been extended to permit subjects still receiving such treatments, but no longer obtaining clinical benefit, to discontinue them and to permit a washout period prior to enrolment in the study.

It is currently planned that the LUCIDITY study will recruit subjects at multiple clinical sites in the US, Canada, UK, Belgium, Poland, Spain and Italy, with these sites becoming active under the new protocol from Q3 2018 to Q1 2019.

Prof Wischik added: "The LUCIDITY study is becoming a more substantial clinical trial but retains its core focus of confirming that treatment with 4 mg LMTX® twice a day as monotherapy is beneficial in patients with Early AD. A positive outcome to this study, in combination with the extensive efficacy and safety data already generated in our previous TRx-237-005 and TRx-237-015 studies, would provide a very credible body of evidence supporting the clinical utility of LMTX® in Alzheimer's disease and endorsing tau aggregation inhibition as a promising therapeutic approach for this tragic condition."

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About Alzheimer's disease

Alzheimer's disease (AD) is a progressive neurologic disease of the brain that causes damage to neurons – the specialized cells of the nervous system that enable the flow of information, thoughts and memories in the brain. When Alzheimer's damages neurons it leads to loss of memory and reasoning, which can affect a person's ability to interact socially or function at work. No treatment yet exists to halt the progression of Alzheimer's-related dementia, delay its onset, or prevent it from occurring. Currently available drugs only treat the symptoms temporarily.

Protein aggregation inhibitors

TauRx's tau aggregation inhibitors (TAIs) have arisen from nearly 30 years of research. TAIs work by undoing the tau tangles that cause dementia, thereby potentially slowing and even arresting memory loss.[4] The first-generation TAI, rember® was a patented, highly-purified version of methylthioninium chloride (methylene blue), a compound previously used to treat a variety of conditions. LMTX® is a stable reduced form of methylthioninium which is better absorbed and is better tolerated than methylene blue and has been tested in clinical trials in mild to moderate Alzheimer's disease.

About TauRx Therapeutics Ltd

TauRx Therapeutics Ltd is a member of the TauRx Pharmaceuticals group which is developing technology spun-out from the University of Aberdeen, Scotland, and was established in Singapore in 2002 with the aim of developing new treatments and diagnostics for a range of neurodegenerative diseases. The company's tau aggregation inhibitor, LMTX®, targets aggregates of abnormal fibres of tau protein that form inside nerve cells in the brain, giving rise to 'tau tangles'. TauRx's headquarters are in Singapore and its primary research facilities are based in Aberdeen. For more information, please visit: http://www.taurx.com.

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