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TauRx meets milestone in pivotal phase 3 Lucidity trial

- **Randomisation now complete across 76 trial sites globally**
- **Recruitment exceeded by ~20 percent**
- **Lucidity is the only late-stage clinical trial targeting the Tau pathology of Alzheimer's**

Aberdeen, Scotland and Singapore [21 April 2021] – TauRx Pharmaceuticals Ltd, the global leader in tau-based research in Alzheimer's disease (AD), today announced it has completed patient randomisation for its Lucidity trial (NCT03446001).

Lucidity is the only late-stage clinical trial specifically targeting the tau pathology of AD. Hydromethylthionine (which TauRx refer to under the chemical abbreviation, LMTM) has already been tested in over 2000 patients in a total of three previous Phase 3 trials in mild and moderate AD, and behavioural variant Frontotemporal Dementia. From these studies, TauRx established that LMTM has consistent pharmacological activity on clinical decline and brain atrophy in both diseases. LMTM is the only experimental drug to date which has shown the ability to reduce the rate at which the brain shrinks irreversibly in these diseases due to loss of neurons and brain connections.

Randomisation means that all study participants that have been screened for inclusion in the trial are now allocated to receive either oral LMTM at a dose of 16 mg/day, oral LMTM at 8mg/day, or placebo. It means the clock starts ticking for the completion of the initial 12 months blinded phase of the study, following which the study data will be available for analysis.

Professor Claude Wischik, Executive Chairman and Co-Founder of TauRx, commented: "Completing randomisation for the Lucidity trial is an important milestone in our quest to confirm the efficacy of LMTM, and we recognise the incredible work of the teams involved in reaching this point in unprecedented circumstances.

"Exceeding our initial target for patient numbers by around 20 percent is testament to the interest in testing tau-based alternatives to drugs targeting amyloid which have been largely unsuccessful so far. The network of esteemed neurological and psychiatric colleagues, patient advocacy groups and people with AD all share a desire to find an effective treatment for this devastating disease, which affects an estimated 50 million people worldwide. We are extremely grateful for their ongoing support. We hope to be able to announce top line trial results some time in Q2 2022."

In light of the ongoing COVID-19 pandemic, TauRx is working closely with all sites to maintain the highest levels of patient safety. The Lucidity trial uses well accepted cognitive and functional assessment scales to confirm the potential benefits seen with LMTM in delaying the progression of AD, and includes an open-label extension phase during which all study participants will receive the drug. The trial also aims to

confirm the reduction in progression of brain atrophy measured by MRI scan that was seen in the earlier trials.

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ABOUT LUCIDITY

The Lucidity trial is designed to confirm the efficacy of LMTM and support regulatory approval of the drug as the first tau-based disease modifying treatment for Mild Cognitive Impairment and Mild-Moderate AD. The results of the previous completed Phase 3 trials found that LMTM has activity at a much lower level than was needed for an oxidised precursor to LMTM, tested in an earlier Phase 2 trial. The results also showed that the drug works better when it is taken alone rather than as an add-on to the standard symptomatic treatments for AD. Previous research has shown that the brain reacts to counteract the boosting effects of symptomatic drugs and this has the secondary effect of reducing the benefits of drugs given later. In light of these results, participants in the trial are given oral LMTM as a monotherapy at a dose of 16 mg/day, which was projected to be the optimal therapeutic dose (Schelter et al. (2019) 931–946 DOI: 10.3233/JAD-190772), 8 mg/day, or placebo.

ABOUT TAURX PHARMACEUTICALS LTD

TauRx research has focused on protein aggregation pathology in Alzheimer's and other neurodegenerative conditions. The company's aggregation inhibitor, hydromethylthionine (LMTM), is currently the only tau-based experimental drug for AD in late stage clinical development in a Phase 3 trial. LMTM targets aggregates of abnormal fibres of tau and TDP-43 proteins that form inside nerve cells in the brain that damage and ultimately kill neurons.

Recently published population-based analyses looking at how blood levels relate to treatment response showed similar concentration-dependent pharmacological activity on clinical decline and brain atrophy in both AD and Frontotemporal Dementia. The predicted optimal dose in AD was found to be 16 mg/day as monotherapy. The Lucidity trial aims to confirm this result by comparing LMTM at a dose of 16 mg/day against placebo in over 500 patients. We hope to report on top line results by Q2-2022 when the last randomised patient completes treatment.

The company was established in Singapore in 2002 with the aim of developing new treatments and diagnostics for a range of neurodegenerative diseases. TauRx's headquarters are in Singapore with primary research facilities and operations based in Aberdeen.

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