TauRx Pharmaceuticals Ltd
3 Shenton Way, #21-04 Shenton House
Singapore 068805

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TauRx completes enrolment of Phase 3 trial and reveals positive new analyses

- **Potentially ground-breaking treatment for the world's greatest unmet medical need**
- **Lucidity trial is the only late-stage clinical trial target the Tau pathology of Alzheimer's**
- **Trial aims to confirm efficacy of first tau-based disease modifying treatment for Alzheimer's**

Aberdeen, Scotland and Singapore [28 January 2021] – TauRx Pharmaceuticals Ltd, the global leader in tau-based research in treatments for Alzheimer's disease (AD), today announced it has completed patient enrolment for the forthcoming Lucidity trial (NCT03446001) ahead of schedule.

Lucidity is the only late-stage clinical trial targeting the tau pathology of Alzheimer's disease (AD). With more than 500 patients, the trial aims to confirm the efficacy of hydromethylthionine (known as LMTM) and support regulatory approval of the drug as the first tau-based disease modifying treatment for Mild Cognitive Impairment and Mild-Moderate AD.

Tau aggregation is now generally understood to be more correlated with clinical decline and reduction in brain metabolism than deposition of amyloid – the main target in clinical trials for the last 20 years.

At the recent J.P. Morgan 39th Annual Healthcare Conference and Biotech Showcase, TauRx data analyses compared cognitive and functional decline in patients receiving LMTM as their sole treatment, with the decline expected on the basis of other reported trial placebo and public data available for comparison. Whereas patients with low blood levels of the drug declined as expected those with levels in the therapeutic range had significantly less decline over 12 months on measures of cognition and general daily function – a reduction of 74% - 100% depending on disease severity.

Professor Claude Wischik, Executive Chairman and Co-Founder of TauRx, commented: "Despite delays due to the COVID-19 pandemic, we are delighted by the speed of recruitment which reflects the interest generated by physicians in this new treatment approach. We are immensely grateful to the study coordinators and investigators, and most importantly, the patients who have volunteered to be part of this potentially ground-breaking clinical trial.

*"*Compared to amyloid-based approaches, LMTM is a convenient, oral treatment with a benign safety profile based on trial results so far, and no risk of amyloid related imaging abnormalities (usually small brain haemorrhages or mild swelling) that are often present with treatments targeting amyloid. Our recent analyses strongly support the concentration-response results we published recently in over 1,000 patients and give us confidence in the outcomes we can expect from the ongoing Lucidity trial.

"There is an urgent need for a treatment targeting the tau pathology of Alzheimer's disease. If the efficacy of LMTM is confirmed, it will open up a completely new treatment direction for a devastating disease

which has so far defied all efforts to bring it under control. Treatments currently available help symptoms for a time, but do not stop disease progression."

In earlier Phase 3 trials, involving over 1,900 patients, LMTM was found to reduce both cognitive decline and brain atrophy, depending on the amount of drug that was absorbed (Schelter et al. 2019 DOI 10.3233/JAD-190772).

TauRx's novel tau aggregation inhibitors (TAIs) target the formation of tau protein 'tangles' in the brain. The spread of tau tangles is strongly correlated with cognitive decline in dementia and they can develop in the brain up to 20 years before symptoms associated with dementia develop. TAIs break down existing tau aggregates and preventing further aggregation of tau protein forming new tangles.

More information on the Lucidity trial can be found at www.luciditytrial.com and educational materials on the role of tau proteins in Alzheimer's disease can be found at www.targetingtau.com.

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ABOUT TAURX PHARMACEUTICALS LTD
TauRx has focused its research on tau pathology in Alzheimer's and other neurodegenerative conditions. Hydromethylthionine (LMTM) is currently the only tau-based drug for AD in a Phase 3 clinical trial. It has already been tested in over 2000 patients in Phase 3 trials in both mild to moderate AD, and behavioural variant Fronto-Temporal Dementia. 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 diseases. 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. Results are expected to be available by mid-2022.

The company was established in Singapore in 2002 with the aim of developing new treatments and diagnostics for a range of neurodegenerative diseases. The company's protein aggregation inhibitor, hydromethylthionine, targets aggregates of abnormal fibres of tau and TDP-43 proteins that form inside nerve cells in the brain. TauRx's headquarters are in Singapore and its primary research facilities and operations are based in Aberdeen.

Media Contacts

Andrew McCallum, Managing Director Aspect: The Strategic Communication Experts andrew.mccallum@aspectreputation.com +44 (0) 7785 467530 Website: http://www.taurx.com Follow TauRx on Twitter at @TauRx	**Leona Minellas, Communication Lead** Aspect: The Strategic Communication Experts Leona.minellas@aspectreputation.com +44 (0) 7311 823947 Website: http://www.taurx.com Follow TauRx on Twitter at @TauRx