ABERDEEN, Scotland and Singapore, 4th September 2016 – TauRx Therapeutics Ltd today announced that its TRx-237-007 Phase 3 clinical trial of the company's second generation tau aggregation inhibitor, LMTX®, in 220 subjects with behavioural variant frontotemporal dementia (bvFTD) failed to achieve its co-primary endpoints. The TRx-237-007 Phase 3 clinical trial, believed to be the largest randomized clinical study ever undertaken in this patient population, adds to the scarce scientific evidence and understanding of this rare condition. Its outcomes and findings will hopefully lead towards therapeutic solutions for these patients in the future.

The study, presented by Professor Claude Wischik, Professor of Psychiatric Geratology at Aberdeen University and co-founder of TauRx at the 10th International Conference on Frontotemporal Dementias (ICFTD) in Munich, did however show that the rate of cognitive decline seen in both the treated and control groups appeared to be less than that seen in previously published studies in bvFTD. The study's inclusion / exclusion criteria appear to have been successful in recruiting a true bvFTD study population, with a clinical severity characterized as mild to moderate. In particular, neuroimaging patterns, changes in whole brain volume and average age as characteristics clearly differentiated this group from patients with mild Alzheimer's disease. Further analyses of the data are in progress, and the full findings of the study are planned for publication in a peer review journal in due course.

LMTX® potentially works by undoing the aggregation of tau protein and TDP-43 protein into the tangles and other lesions associated with dementia in bvFTD. Approximately half of bvFTD patients have a specific pathology that involves aggregation of tau protein in the brain. The other half have a pathology that involves the aggregation of a protein called TDP-43.[1] Based on studies in cell models, LMTX® may also have activity as an inhibitor of aggregation of the protein TDP-43 in addition to blocking the aggregation of tau protein.

There were no differences in the cognitive (ACE-R) and functional (FAQ) assessment or brain imaging (whole brain volume via MRI) primary outcomes, nor in the key secondary efficacy outcomes, between the high dose (100 mg twice a day) group and the low dose (4 mg twice a day) control group. The safety profile of LMTX® seen in this study was consistent with that seen in two larger studies of the drug in patients with Alzheimer's disease.

-Ends-

About Study TRx-237-007 and the LMTX® Phase 3 trials

Study TRx-237-007 was a randomized double-blind placebo-controlled trial in 220 patients with bvFTD that compared treatment for 52 weeks with high dose LMTX® (100 mg twice a day) with a low dose (4 mg twice a day) used as a control. The low dose was included as the control in order to ensure blinding between the study populations, as taking LMTX® can be associated with urinary discolouration. The primary efficacy endpoints were cognitive decline, functional decline, and brain atrophy as measured respectively by ACE-R, FAQ and MRI. This trial is part of the Phase 3 programme of LMTX® in Alzheimer's disease and bvFTD.

About behavioural variant frontotemporal dementia

Frontotemporal dementia (FTD) is a neurodegenerative syndrome characterised by progressive deficits in behaviour, mental function, and language. Behavioural variant FTD (bvFTD) is the most common type of FTD; it is particularly aggressive and progresses faster than Alzheimer's disease. FTD is the second most common form of dementia across all age groups after Alzheimer's disease.[1] In the United States, FTD affects 15 to 22 people per 100,000 in the population; 70% of these cases are bvFTD. In addition, up to 26% of people with early-onset dementia have FTD.[1] There are currently no treatments available that can affect the progression of FTD. Instead, treatments are aimed at modifying behavioural symptoms.

About Tau 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 slowing and even arresting memory loss.[2] LMTX® is a stable reduced form of methylthioninium.

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.

References

1. Bang J, et al. (2015) Frontotemporal dementia. Lancet 386:1672-82.
2. Wischik CM, et al. Tau-aggregation inhibitor therapy for Alzheimer's disease. Biochem Pharamcol 2014;88:529–39.

TauRx Pharmaceuticals Ltd. 3, Shenton Way, #21-04, Shenton House, Singapore 068805, Republic of Singapore
TauRx Therapeutics Ltd. 3, Shenton Way, #21-04, Shenton House, Singapore 068805, Republic of Singapore
TauRx Research Facility Liberty Building, Foresterhill Road, Aberdeen AB25 2ZP, UK
For further information **visit www.taurx.com**

Media Contacts

Email: taurxpress@hkstrategies.com

Website: http://www.taurx.com