



**STRICTLY EMBARGOED UNTIL 08:00, 27 July 2016 EST (Toronto, Canada)**

## **TauRx Reports First Phase 3 Results for LMTX<sup>®</sup>**

### **Promising Read-Out for First-Ever Tau Aggregation Inhibitor to Enter Phase 3 Trials**

- **LMTX<sup>®</sup> as monotherapy demonstrates significant reductions in disease progression in mild and moderate Alzheimer's disease**
- **Strong results in both cognitive and functional tests supported by brain scan evidence of slow-down in progression of pathology**
- **Study misses co-primary endpoints as LMTX<sup>®</sup> as add-on therapy shows no beneficial effects**
- **Initial analysis from second phase 3 study in patients with mild Alzheimer's disease confirm positive findings**

**ABERDEEN, Scotland and SINGAPORE, 27 July 2016** – TauRx Therapeutics Ltd today announced Phase 3 clinical trial results that show treatment with LMTX<sup>®</sup>, the company's novel tau aggregation inhibitor, had a marked beneficial effect on key measures of Alzheimer's disease in patients with mild or moderate forms of the disease.

While the TRx-237-015 study in 891 subjects failed to meet its co-primary endpoints, clinically meaningful and statistically significant reductions in the rate of disease progression were observed across three key measures in patients who were treated with LMTX<sup>®</sup> as their only Alzheimer's disease medication. These three key measures comprised a cognitive assessment (ADAS-Cog), a functional assessment (ADCS-ADL) and an assessment of the level of brain atrophy (lateral ventricular volume, LVV, as measured by MRI). An abstract of the results will be presented during an open session at the 2016 Alzheimer's Association International Conference (AAIC) in Toronto, Canada this afternoon by Dr. Serge Gauthier, CM, MD, FRCPC, Director of the Alzheimer's Disease Research Unit, McGill University, Canada.

“In a study of this size across a combined mild to moderate patient population, it is both encouraging to see improvements of this magnitude in the standard cognitive and functional tests and reassuring to see the

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supporting brain scan evidence of a slowing in disease progression during 15 months of treatment,” said Dr. Gauthier, “As a practicing clinician I see Alzheimer’s patients, their families and care-givers every day, and continually share their desperate need for a truly therapeutic product as today we only have symptomatic treatments available to us. In a field that has been plagued by consistent failures of novel drug candidates in late-stage clinical trials and where there has been no practical therapeutic advance for over a decade, I am excited about the promise of LMTX<sup>®</sup> as a potential new treatment option for these patients.”

The same efficacy findings were not seen in study patients who took LMTX<sup>®</sup> in combination with other standard Alzheimer’s treatments. Since these patients formed the substantial majority of those recruited to the trial, the treatment benefits seen in those taking LMTX<sup>®</sup> as monotherapy could not be seen when all patients taking LMTX<sup>®</sup> were pooled in the primary analysis model. Although this prevented the study from achieving an overall statistical significance in the pooled analysis, the primary analysis model showed a highly significant effect of treatment in the patients taking LMTX<sup>®</sup> as monotherapy. This treatment benefit was confirmed in a prespecified supportive analysis of all of the study’s primary and secondary outcomes. This is the first treatment in which a clinical effect has been supported by evidence in delay of progression in brain atrophy shown by MRI scans.

Professor Claude Wischik, Professor of Psychiatric Geratology at Aberdeen University and co-founder of TauRx said, “The results we have seen in this study confirm the results we saw in our Phase 2 study, where an earlier version of the drug was also given as monotherapy. The results we see in those patients not taking Alzheimer’s disease medications show the considerable potential of LMTX<sup>®</sup> as a monotherapy for both mild and moderate Alzheimer’s disease. Perhaps more importantly, these results support the targeting of the tau tangle pathology in Alzheimer’s disease as being a very promising drug development pathway. However, the reason for the observed loss of efficacy of LMTX<sup>®</sup> when taken in combination with currently available treatments for Alzheimer’s disease is not as yet understood.”

An initial analysis of data from the second of TauRx’s two Phase 3 trials in Alzheimer’s disease, study TRx-237-005 undertaken in 800 patients with the mild form of the disease, confirms the findings of study TRx-237-015 and supports the potential of LMTX<sup>®</sup> as monotherapy. The results from this study are expected to be published and presented later in 2016.

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### Impact of LMTX<sup>®</sup> Treatment on Key AD Measures

- The ADAS-cog decline analysis produced highly statistically significant treatment effects of -6.3 +/- 1.4 (p<.0001) and -5.8 +/-1.4 (p<.0001) units after taking 75mg b.i.d or 125mg b.i.d of LMTX<sup>®</sup> as monotherapy respectively, while the ADCS-ADL decline analysis produced a statistically significant treatment effect of 6.5 +/-1.8 (p=.0013) and 6.9 +/-1.9 (p=.0007) following treatment of 75mg b.i.d or 125mg b.i.d of LMTX<sup>®</sup> as monotherapy respectively.
- LMTX<sup>®</sup> taken as monotherapy also slowed down the rate of progression of brain atrophy as measured by LVV derived from MRI scans. There was a reduction in the expansion of the LVV by 38%+/-9% (p=.0023) and 33%+/-9% (p=.0014) for 75mg twice a day and 125mg twice a day, respectively, compared to the control in these patients. These reductions in LVV expansion were statistically significant and confirmed by corresponding increases in the whole brain volumes in the same patient groups.
- In those study patients taking LMTX<sup>®</sup> as add-on therapy to current AD medications, there were no statistically significant differences in ADAS-cog, ADCS-ADL or LVV measurements between the control, 75mg b.i.d LMTX<sup>®</sup> or 125 mg b.i.d. LMTX<sup>®</sup> treatment groups.

-ENDS-

### About Study TRx-237-015

Study TRx-237-015, was a randomized double-blind placebo-controlled study in 891 subjects with mild or moderate Alzheimer's disease that compared treatment for 15 months with LMTX<sup>®</sup> with placebo. The safety profile of LMTX<sup>®</sup> in the study was acceptable, with rates of amyloid-related imaging abnormalities reported similar to placebo arms in recent Phase 3 trials and with the overall adverse event profile also similar to those typically seen in Phase 3 studies of novel late-stage Alzheimer's disease treatments. The most common adverse events occurred in the gastrointestinal and urinary tracts, and were typically mild in nature and easily controlled.

### Data Presentation Details

Study TRx-237-015 will be presented at an oral session at AAIC on 27 July 2016, 16:15-17:45.

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## **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<sup>1</sup>. The first-generation TAI, rember<sup>®</sup>, was a patented, highly-purified version of methylene blue, a compound previously used to treat a variety of conditions.

## **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<sup>®</sup> 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. Wischik CM, et al. Tau-aggregation inhibitor therapy for Alzheimer's disease. *Biochem Pharmacol* 2014;88:529-39.

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