

PRESS RELEASE

Tau-targeting Alzheimer's treatment, HMTM, moving toward regulatory submission based on initial data from TauRx's LUCIDITY trial

- LUCIDITY data suggest that participants receiving hydromethylthionine mesylate (HMTM) decline at a rate substantially less than is typical in Alzheimer's based on published research
- Safety profile is favourable and consistent with previous HMTM studies
- TauRx will now pursue regulatory submission and coverage for HMTM

Aberdeen, UK and Singapore, May 31, 2022 – TauRx Pharmaceuticals Ltd, the global leader in tau-based research in Alzheimer's, today announced unblinding of initial data from completion of the randomised portion of their pivotal Phase 3 clinical trial, LUCIDITY (NCT03446001).

TauRx's lead investigative oral drug, HMTM, has been tested in 598 people with Alzheimer's. Following our 12 month blinded phase of the study, participants have moved forward to an additional one year open label phase.

Professor Claude Wischik, Executive Chairman and Co-Founder of TauRx, commented: "The output indicates that participants receiving HMTM decline at a rate substantially less than is typical in Alzheimer's based on published research. This was seen for both cognitive and functional endpoints across a broad range of severity from mild cognitive impairment (MCI) to moderate Alzheimer's. Importantly, the safety profile is favourable and consistent with previous studies.

"Our data analysis is ongoing and will be reported at a later date. We look forward to providing an update on our progress on 9th June 2022 at the 35th Global Conference of Alzheimer's Disease International.

"Our expert advisors including EVERSANA are confident in our moving toward regulatory submission and gaining coverage for HMTM.

"Today with limited treatments for Alzheimer's, the standard of care does not impact the underlying causes of symptom progression. HMTM aims to significantly slow disease progression, providing longer term benefits compared to medications brought to market almost twenty years ago."

Prior to the release of the LUCIDITY interim data, the UK Medicines & Healthcare products Regulatory Agency (MHRA) granted the company an Innovation Passport on 18th May 2022. The Innovation Passport is the first stage of the Innovative Licensing and Access Pathway (ILAP), which is intended to accelerate development and approval times, facilitating access to new products and indications.

Professor Wischik explains, "The ILAP designation represents a clear signal of regulatory support for a prospective treatment breakthrough in Alzheimer's, which remains one of the world's greatest unmet medical needs. Dementia is a leading cause of death around the world, and the Innovation Passport, as the first stage of the ILAP scheme, enables access to the collaborative approach of regulators and associated health technology assessment bodies to both drug licensing and access throughout the UK.



“We recognise and publicly thank the incredible commitment from participants and partners involved in LUCIDITY. Our scientific focus on the role of tau pathology in neurodegenerative disease with support from our shareholders and team has enabled us to reach this important milestone.”

With the vision to change the diagnostic and dementia care landscape, the joint venture between TauRx and Genting Berhad, GT Diagnostics, continues to move forward with developing new diagnostic tau biomarker and psychometric tools. These tools will aid in earlier and more accurate identification of people with Alzheimer’s and are designed to assist in management through the progression of symptoms.

With an estimated 50 million people worldwide with Alzheimer’s, their families, healthcare professionals and society, TauRx share their aim in finding a safe and effective management.

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ABOUT LUCIDITY

LUCIDITY is the only late-stage clinical trial specifically targeting the tau pathology of Alzheimer's. Aggregation of abnormal tau protein is one of the hallmark pathologies. Tau aggregation and the subsequent formation of tau tangles disrupt neuronal function, a process that begins many years before symptoms of dementia are seen. Tau pathology correlates strongly with Alzheimer's severity and the clinical decline (loss of memory and ability to care for one's self) commonly seen in people with Alzheimer's.

The LUCIDITY trial is designed to confirm the efficacy of HMTM* and support regulatory submission as the first disease modifying Alzheimer's treatment for Mild Cognitive Impairment and Mild-to-Moderate stages. The trial background and design are described in an upcoming paper in the Journal of Prevention of Alzheimer's Disease (JPAD).

*Previously also abbreviated to LMTM and LMTX.

<https://www.luciditytrial.com/>

ABOUT TAURx PHARMACEUTICALS LTD

In 2002 TauRx Therapeutics Ltd. was established in Singapore, in our continuing partnership with the University of Aberdeen. The company has dedicated the past two decades to developing treatments and diagnostics for Alzheimer's and other neurodegenerative diseases due to protein aggregation pathology. TauRx's primary research facilities and operations are based in Aberdeen, UK.

<https://www.taurx.com/>

ABOUT GT DIAGNOSTICS

Genting TauRx Diagnostic Centre Sdn Bhd, a company established in Malaysia, and its wholly owned subsidiary GT Diagnostics (UK) Limited (collectively, "GT Diagnostics") was founded as a collaboration between Genting Berhad and TauRx Pharmaceuticals Ltd Group and is currently developing new tau biomarker and psychometric tools for people with Alzheimer's, caregivers and clinicians for early detection of Alzheimer's. GT Diagnostics currently develops readily deployable e-platform tools for home use as well-being apps, alongside professional tools for expert use to aid diagnosis and monitoring of dementias.

<https://www.gtdiag.com/>

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