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Phase 3 clinical trial begins in early form of dementia

Investigational drug study follows earlier study with promising results in mild to moderate Alzheimer's patients

Manchester, UK – TauRx Therapeutics today announced the initiation of a global Phase 3 clinical trial in a type of Frontotemporal Dementia (FTD) also known as Pick's Disease. The announcement, which immediately follows The 8th International Conference on Frontotemporal Dementias, held 5-7 September in Manchester, England, underscores the need for new treatments for this form of dementia that is similar to Alzheimer's Disease, except that it tends to damage different areas of the brain and affects people as early as 40 years old.

The study focuses on a type of FTD known as behavioural-variant, or bvFTD, which can cause early changes in personality and loss of empathy. A large percentage of these patients have a specific pathology that involves abnormal collections of tau protein in the brain.

The study drug, LMTX™, targets a process in the brain whereby a normal form of tau protein begins to self-aggregate due to binding neuronal waste-products. Once the process has started, the aggregates are able to propagate themselves indefinitely, using up normal tau protein and converting it into the toxic aggregates. After destroying the nerve cells where they are initially formed, the aggregates go on to infect nearby healthy neurons, progressively spreading and accelerating the destruction throughout the brain. LMTX™ stops this aggregation process in its tracks and releases the trapped tau protein in a form which can be easily cleared by nerve cells.

In a pilot series of cases, LMTX™ was found to arrest the progression of the disease. LMTX™ has been found to act in a similar way on the aggregation of TDP-43 protein. Tau or TDP-43 aggregates each account for about 50% of patients with this early form of dementia.

Speaking to patients and caregivers at the FTD conference in Manchester, Professor Bradley Boeve of the Mayo Clinic in the U.S., one of the investigators of the study, said: “Clinicians devoted to FTD clinical trial development have been refining the measures to use in an experimental trial in FTD spectrum disorders for years, and frankly have been waiting for a promising agent. The basic science data for this agent, particularly in the tauopathies, looks sound and the excitement among investigators and among families is high.”

The Phase 3 double-blind placebo-controlled study is designed to evaluate the safety and efficacy of LMTX™, the second-generation Tau Aggregation Inhibitor (TAI) developed by TauRx. The study aims to confirm the results first seen in the pilot cases in a larger controlled clinical trial in bvFTD patients over a 52-week timeframe. Participating study sites are located in Canada, U.S., U.K., Germany, The Netherlands, Australia and Singapore. Because the condition is relatively rare, TauRx was granted Orphan Designation for LMTX™ in 2010, which provides a basis for more rapid approval for marketing if the trial is successful.

“This is an important step forward in our quest to find an effective treatment, with a goal to actually arrest the progression of the disease,” said Professor Claude Wischik, founder and CEO of TauRx Therapeutics and Professor of Old Age Psychiatry at the University of Aberdeen. “We are building on over thirty years of research, and the encouraging results from our previous Phase 2 clinical trial in Alzheimer’s Disease, which is also correlated with abnormal tau aggregates in the brain.”

TauRx previously tested **rember©**, the first-generation TAI on which LMTX™ is based, in a Phase 2 clinical trial involving 321 patients with mild and moderate Alzheimer’s Disease in the UK and Singapore. This study found a 90% reduction in the rate of disease progression over two years in Alzheimer’s Disease. Professor Wischik and his team have spent nearly 24 years investigating the structure and role of Tau tangles in the development of Alzheimer’s disease, FTD and other neurodegenerative diseases. They were the original discoverers of the Tau protein pathology of Alzheimer’s.

“It’s very exciting news that a treatment is being tested for FTD in a clinical trial,” said Penelope Roques of the Frontotemporal Dementia Support Group in the UK. “This is

encouraging progress in a disease where there is currently no treatment available." The group has about 1,000 members across the UK, ranging from FTD patients, caregivers and family members.

If successful, this will be the first investigational drug that is able to arrest the progression of this disease. TauRx Therapeutics, a Singapore-based company spun out of the University of Aberdeen, developed the novel treatment based on an entirely new approach which targets aggregates of abnormal fibres of tau protein that form inside nerve cells in the brain. The TauRx team have since discovered that LMTX™ could also have beneficial effects on other proteins which aggregate abnormally, including TDP-43 in FTD and synuclein in Parkinson's disease. In FTD, the frontal and temporal lobes are affected first, which impacts behaviour and emotion. As the disease progresses, other parts of the brain are affected, eventually producing a global dementia.

Patients and caregivers are invited to sign up for future updates as more news is available at www.PicksDementiaStudy.info.

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About Pick's Disease:

According to the Association for Frontotemporal Degeneration (AFTD), bvFTD – or Pick's disease as it was originally known – can cause early and progressive changes in personality, emotional 'blunting' and loss of empathy. A person with the disorder may have difficulty controlling their behaviour, which can result in socially inappropriate responses or actions. Language may also be impaired after behavioural changes take place, as well as neurological symptoms such as movement and coordination difficulties. Over time, these symptoms worsen. The bvFTD form of the disease is particularly aggressive and progresses faster than Alzheimer's disease.

About TauRx:

TauRx Therapeutics was established in Singapore in 2002 with the aim of developing new treatments and diagnostics for a range of neurodegenerative diseases based on its technology platform. The TauRx team includes highly skilled and internationally recognised pharmaceutical experts in drug discovery and development. The

company's Tau Aggregation Inhibitors (TAIs) include **rember**® and LMTX™, the second-generation drug that is being studied in Phase 3 clinical trials in Alzheimer's and FTD. TauRx is headquartered in Singapore with primary research facilities in Aberdeen, Scotland.

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