



Theranexus Announces the First European Approval for its Phase 2 Clinical Trial with THN 102 in Parkinson's Disease Patients

 **FIRST GREEN LIGHT FOR THE LAUNCH OF AN INTERNATIONAL MULTICENTRE PHASE 2 STUDY**

Lyon, 19 April 2018 – Theranexus, a biopharmaceutical company innovating in the treatment of neurological diseases and pioneer in the development of drug candidates acting on the interaction between neurons and glial cells, announces today that it has received approval from the Hungarian Medicines Agency for the phase 2 clinical trial of its THN102 drug candidate in Hungary for people with EDS related to Parkinson's disease.

Entitled "Randomised, double-blind, placebo controlled, complete 3-way cross-over phase 2a trial to investigate safety and efficacy of two THN102 doses in subjects with excessive daytime sleepiness associated with Parkinson's disease" and coordinated by Professor Jean-Christophe Corvol of Pitié Salpêtrière Hospital in Paris, the study will be conducted in more than 20 centres in Europe (France, Germany, Hungary, Czech Republic) and the United States. Its objective is to evaluate the clinical benefit of the drug candidate THN102 in 60 patients with Parkinson's disease suffering from EDS. Other national regulatory authorisations are still being awaited for other countries before the geographical footprint of the study can be finalised. As previously announced, the results of this study are expected in the second quarter of 2019.

"We would like to thank the regulatory agencies with whom we are in contact and we are delighted with this first authorisation for the phase 2 study for our drug candidate THN102 in Parkinson's disease," said Franck Mouthon, Chief Executive Officer of Theranexus.

ABOUT THN102

THN102 (modafinil/flecainide combination) for the treatment of wakefulness impairment in narcolepsy and Parkinson's disease is the most advanced drug candidate developed by Theranexus. Having demonstrated its superior performance compared with the standard treatment in healthy volunteers, it is currently in phase II in narcolepsy, an orphan disease affecting approximately 300,000 patients in Europe and the United States and representing a market valued at \$2 billion. At the same time, THN102 will begin another phase II clinical trial on excessive daytime sleepiness in Parkinson's disease, the second-most common neurodegenerative disease. Excessive daytime sleepiness is a debilitating symptom, closely associated with attention and cognition disorders in the disease. There is currently no authorised treatment for the management of this symptom, which affects 30% of patients with Parkinson's disease. These two phase II trials represent an opportunity for strong value creation by 2019 to be materialised through an industrial partnership.

ABOUT THE STUDY IN PARKINSON'S DISEASE

This study is a randomised, double-blind, placebo-controlled, complete 3-way cross-over phase 2a trial to investigate safety and efficacy of two THN102 doses in subjects with excessive daytime sleepiness associated with Parkinson's disease, meaning that each patient will receive all of the following treatments successively and in a random order: THN102 200mg modafinil/2mg flecainide, THN102 200mg modafinil/18mg flecainide, and a placebo. This study will be coordinated by Professor Jean-Christophe Corvol of Pitié Salpêtrière Hospital in Paris and will be conducted in more than 20 centres in Europe (France, Germany, Hungary, Czech Republic) and in the United States. The study will include 60 patients with Parkinson's disease who suffer from Excessive Daytime Sleepiness, characterised by an Epworth Sleepiness Scale score of 14 (out of 24) or higher. The primary endpoint of the study is treatment tolerance in these patients, with secondary endpoints including an evaluation of sleepiness, vigilance, and cognition.

For more information regarding Theranexus Parkinson's trial, patients can visit: <https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-004475-31/HU>

ABOUT THERANEXUS

Theranexus is a clinical-stage biopharmaceutical company that emerged from the French Alternative Energies and Atomic Energy Commission (CEA) in 2013. It develops drug candidates for the treatment of nervous system diseases. Theranexus identified the key role played by non-neuronal cells (also known as "glial cells") in the body's response to psychotropic drugs (which target the neurons). The company is a pioneer in the design and development of drug candidates affecting the interaction between neurons and glial cells. The unique, patented technology used by Theranexus is designed to improve the efficacy of psychotropic drugs already approved and on the market, by combining them with a glial cell modulator. This strategy of combining its innovations with registered drugs means Theranexus can significantly reduce development time and costs and considerably increase the chance of its drugs reaching the market.

The proprietary, adaptable Theranexus platform can generate different proprietary drug candidates offering high added-value for multiple indications.

Theranexus is listed on the Euronext Growth market in Paris (FR0013286259- ALTHX).

More information at: www.theranexus-bourse.com



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