



# Theranexus

SHIFTING THE LINES AGAINST  
CENTRAL NERVOUS SYSTEM  
DISORDERS



## THERANEXUS ANNOUNCES GERMAN AUTHORITIES APPROVAL FOR ITS PHASE 2 CLINICAL TRIAL IN PARKINSON'S DISEASE

**Lyon, 26 June 2018** – Theranexus, a biopharmaceutical company innovating in the treatment of neurological diseases and pioneer in the development of drug candidates modulating the interaction between neurons and glial cells, today announces that it has received approval from the German Medicines Agency to launch the opening of the sites for the phase 2 clinical trial of its THN102 drug candidate in Germany for people with Excessive Daytime Sleepiness (EDS) related to Parkinson's disease.

After receiving Investigational New Drug (IND) status from the Food & Drug Administration (FDA) in the United States, Theranexus has now obtained a further European approval for its multicentre clinical study which will be conducted in more than 20 centres in five countries (United States, France, Germany, Hungary, Czech Republic). This study aims to evaluate the clinical benefit of the drug candidate THN102 in 60 patients suffering from Parkinson's disease as well as from EDS.

*“We are pleased to announce this approval in Germany which will allow the opening of several centres for the phase 2 Parkinson's study. In the coming weeks, the first patients will be recruited by our network of clinicians under the leadership of Professor Jean-Christophe Corvol of the Pitié Salpêtrière Hospital in Paris, principal investigator of the study,”* said Franck Mouthon, CEO of Theranexus.

The results of this study are expected in the second quarter of 2019.

### ABOUT THN102

THN102 (modafinil/flecainide combination) for the treatment of wakefulness impairments 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 impairment of attention and cognition 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.

## 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.com](http://www.theranexus.com)



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