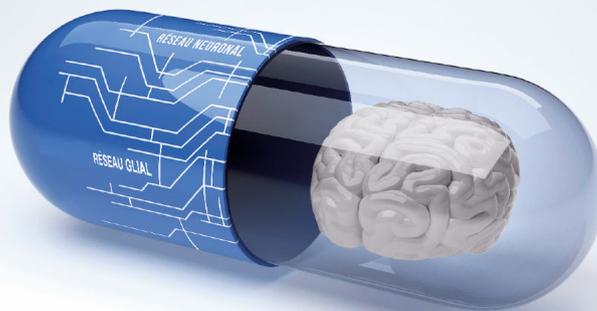




# Theranexus

SHIFTING THE LINES AGAINST  
CENTRAL NERVOUS SYSTEM  
DISORDERS



## Theranexus Announces the Inclusion of the First Patient in its Phase 2 Clinical Trial Evaluating its Drug Candidate THN102 in Excessive Daytime Sleepiness (EDS) in Patients with Parkinson's Disease

- Evaluation of THN102 in 60 patients in over 20 centres in Europe and the United States
  - Results of the study expected in mid 2019

**Lyon, 16 July 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 is announcing today the inclusion of its first patient suffering from Excessive Daytime Sleepiness (EDS) in Parkinson's disease in its phase 2 clinical trial evaluating its drug candidate THN102.

Excessive Daytime Sleepiness<sup>1</sup> is a tendency to fall asleep at times when you are normally awake. It is a very common and debilitating symptom<sup>2</sup> in Parkinson's patients<sup>3</sup>. There is currently no authorised treatment for this symptom in Parkinson's patients.

The study will be conducted in more than 20 centres in Europe and the United States. It will include 60 patients with Parkinson's disease who suffer from EDS characterised by an Epworth Sleepiness Scale score of 14 (out of 24) or higher. This will be a double-blind, placebo-controlled study with crossover design, in other words each patient will receive all of the following treatments successively for 2 weeks and in random order: THN102 200mg modafinil / 2mg flecainide, THN102 200mg modafinil / 18mg flecainide or a placebo. The primary endpoint of the study is treatment tolerance of the drug candidate THN102 in these patients, with secondary efficacy endpoints including an evaluation of sleepiness, vigilance and cognition.

*"We are pleased to announce the inclusion of the first patient suffering from EDS in our phase II clinical trial in Parkinson's disease. Excessive Daytime Sleepiness is a debilitating non-motor symptom, and is a considerable accident risk factor<sup>4 5</sup> which affects between 20 and 50% of patients with Parkinson's disease - the second most common neurodegenerative disease. Our results will be available by mid 2019,"* explains Dr Werner Rein, the Chief Medical Officer of Theranexus.

*"There is currently no approved treatment for reducing EDS in Parkinson's disease, which is a very debilitating symptom for the patients and their families. THN 102 is a highly promising drug candidate which has already demonstrated, in phase I, its safety and efficacy in healthy volunteers compared with modafinil alone, the goldstandard wakefulness-promoting drug,"* concludes Prof. Jean-Christophe Corvol of Hôpital de la Pitié Salpêtrière, the principal investigator of the study.

<sup>1</sup> Arnulf I. Excessive daytime sleepiness in parkinsonism. Sleep Medicine Reviews (2005) 9, 185-200 - <https://www.ncbi.nlm.nih.gov/pubmed/15893249>

<sup>2</sup> Knie B. Excessive daytime sleepiness in patients with Parkinson's Disease. CNS Drugs 2011; 25 (3): 203-212- <https://www.ncbi.nlm.nih.gov/pubmed/21323392>

<sup>3</sup> Salawu F and Olokoba A. Excessive daytime sleepiness and unintended sleep episodes associated with Parkinson's Disease - <https://www.ncbi.nlm.nih.gov/pubmed/25829994>

<sup>4</sup> Spindler M. Daytime sleepiness is associated with falls in Parkinson's disease. J. Parkinson's Dis. 2013; 3(3): 387-391. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3772981>

<sup>5</sup> Ondo W. Daytime sleepiness and other sleep disorders in Parkinson's Disease. Neurology 2001 ; 57 : 1392-1396. <https://www.ncbi.nlm.nih.gov/pubmed/11673578>

## 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 sleep-deprived 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 begins 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 20 to 50% 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.

For more information on the Phase II multicentric trial and its inclusion criteria, 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.com](http://www.theranexus.com)



## Contacts

### THERANEXUS

**Thierry Lambert**

Financial and Administrative Director  
[investisseurs@theranexus.fr](mailto:investisseurs@theranexus.fr)

### ACTUS finance & communication

**Caroline Lesage / Théo Martin**

Investor Relations  
+33 (0)1 53 67 36 79 / +33 (0)1 53 67 36 75  
[theranexus@actus.fr](mailto:theranexus@actus.fr)

### FP2COM

**Florence Portejoie**

Media Relations  
+ 33 (0)6 07 76 82 83  
[fportejoie@fp2com.fr](mailto:fportejoie@fp2com.fr)