Theranexus

SHIFTING THE LINES AGAINST CENTRAL NERVOUS SYSTEM DISORDERS


# THN102 OBTAINS INVESTIGATIONAL NEW DRUG STATUS FROM THE FOOD & DRUG ADMINISTRATION (FDA)

- GREEN LIGHT FOR THE LAUNCH OF A PHASE 2 STUDY IN THE UNITED STATES
- ACCESS TO THE 505(b)(2) PATHWAY GAINED, REDUCING THE DEVELOPMENT NECESSARY FOR REGISTRATION IN THE UNITED STATES

Lyon, April 23, 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 the success of its efforts to obtain the Investigational New Drug (IND) Status from the United States Food & Drug Administration (FDA) for THN102. This status officially triggers the opening of the regulatory dossier for THN102 on the US territory until its registration and for all indications that could be approved.

The IND status was obtained as part of the clinical development of this drug candidate in the treatment of Excessive Daytime Sleepiness (EDS) associated with Parkinson's disease. It therefore authorises the phase 2 clinical trial to assess the clinical benefit of the THN102, a combination of modafinil and flecainide in 60 patients with Parkinson's disease and suffering from EDS. This clinical trial will be conducted in Europe and the United States in more than 20 sites, including three sites in the United States. As previously announced, the results of this study are expected in the second quarter of 2019.

## A development strategy reinforced on the US market

Beyond the authorisation to conduct a phase 2 study in the United States, obtaining the IND status confirms certain key points of the regulatory development strategy for THN102 on the US market. In particular, Theranexus was able to confirm that THN102 would be eligible for the 505(b)(2) approval pathway at the end of its regulatory development. This pathway offers the opportunity to benefit from the extensive data available for currently registered molecules included in the exclusive composition of the combination, which reduces the remaining necessary work for the Company ahead of its registration.

"Obtaining the IND status from the FDA is a critical step in the development of our drug candidate THN102. It confirms our desire to develop THN102 also in the United States, which remains our industry's largest market", explained Franck Mouthon, Chief Executive Officer of Theranexus. "Now that this milestone has been achieved, THN102 is officially registered as a 505(b)(2) drug candidate with the US agency, which significantly boosts its interest in the eyes of industrial players who see this market as central to their strategy", continued Franck Mouthon.

## 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-bourse.com

## Contacts

### THERANEXUS
**Thierry Lambert**
Financial and Administrative Director
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

### FP2COM
**Florence Portejoie**
Media Relations
+ 33 (0)6 07 76 82 83
fportejoie@fp2com.fr