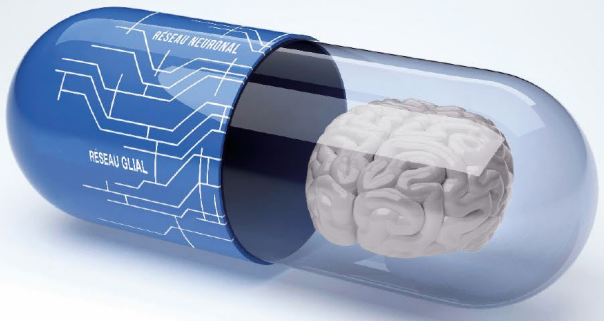
PRESS RELEASE

Theranexus

SHIFTING THE LINES AGAINST CENTRAL NERVOUS SYSTEM DISORDERS



THERANEXUS ANNOUNCES THE SUCCESS OF ITS PHASE II TRIAL FOR THN102 IN PARKINSON'S PATIENTS

- *THN102 met the primary efficacy endpoint by significantly reducing excessive daytime sleepiness in Parkinson's patients*
- *THN102 consistently increased the proportion of patients no longer suffering from daytime sleepiness during treatment*
- *Excellent tolerability in these Parkinson's patients*

Lyon, FRANCE March 31, 2020 – Theranexus, a biopharmaceutical company innovating the treatment of neurological diseases and pioneering the development of drug candidates modulating the interaction between neurons and glial cells, has announced the success of its Phase II trial for drug candidate THN102 for Parkinson's disease.

Seventy-five Parkinson's patients with debilitating, excessive daytime sleepiness (EDS) were recruited in Europe and the United States. The study was a double-blind, placebo-controlled, crossover trial with a one-week washout period between each successive two-week treatment period. The treatments were given in random order and consisted of: THN102 200mg modafinil/2mg flecainide, THN102 200mg modafinil/18mg flecainide, or a placebo.

THN102 met the primary efficacy endpoint and significantly increased the proportion of patients no longer suffering from daytime sleepiness for the duration of the treatment

The trial demonstrated the efficacy of THN102 in doses of THN102 200mg modafinil/2mg flecainide ("THN102-200/2"), with significant superiority over the placebo in reducing EDS measured using the Epworth Sleepiness Scale (ESS – the most widely used sleepiness scale, ranging from 0 to 24). The ESS score improved by 3.9 points in patients after treatment with THN102-200/2. This improvement is highly significant (p=0.01) compared with that achieved by the placebo (2.4 points).

The proportion of patients no longer presenting excessive daytime sleepiness for the duration of the treatment (commonly defined as ESS<11, Johns, 1997) was considerably higher with THN102-200/2 than in the placebo group (27.5% v. 16.2% – p=0.05).

The other exploratory efficacy parameters used in the trial did not show a difference between THN102 and the placebo.

An excellent tolerability profile

The trial demonstrated the excellent tolerability profile of THN102 for the two doses tested. The trial also provided assurance, via various sections of the Unified Parkinson's Disease Rating Scale (UPDRS – the most widely used scale for Parkinson's disease), that THN102 did not affect the motor disorders or other symptoms that occur in patients.

A more detailed presentation of the results of the trial is now available on the company website.

Professor Jean-Christophe Corvol at Pitié Salpêtrière Hospital and the Brain Institute, a Parkinson's disease specialist and principal investigator for the trial, noted: *"With aging populations and increasing numbers of elderly people, the number of patients affected by Parkinson's disease will continue to rise. The symptom addressed by THN102 – excessive daytime sleepiness in Parkinson's disease – affects around 40% of patients. It is particularly debilitating[1] [2] and represents one of the primary risk factors[3] for accidents, with considerable medical and economic consequences.[4] There is currently no approved treatment to mitigate these major impacts. The positive results achieved with THN102 in this trial are a tremendous step forward in treating this debilitating symptom."*

Franck Mouthon, CEO of Theranexus, added, *"We have taken a crucial step forward in the development of our most advanced drug candidate, THN102. I would like to thank all the patients and practitioners who contributed to the success of this trial. To our knowledge, THN102 is the only pharmaceutical development with demonstrated efficacy for this indication, affecting about 2 million patients in the major markets. The aim for Theranexus is now to join forces with an industrial partner to continue developing THN102. Finally, in addition to the value of this Phase II success for THN102, this new step also represents a significant endorsement of the therapeutic approach pursued by Theranexus and its potential for efficacy in patients."*

ABOUT EXCESSIVE DAYTIME SLEEPINESS IN PARKINSON'S DISEASE[5]

Excessive daytime sleepiness is the inability to stay awake and alert during waking hours. It can also cause unpredictable and irresistible sudden sleep attacks.

Sleepiness generally manifests itself during periods of inactivity (or reduced activity), such as reading or watching television, but it can also occur when driving if the car is at a standstill, for example when stuck in a traffic jam.

The prevalence of excessive daytime sleepiness is higher in Parkinson's disease patients than in the general population. It is thought that around 40% of people with Parkinson's disease suffer from excessive daytime sleepiness. These sleepiness episodes may be aggravated by dopaminergic drugs, and their frequency increases as the disease progresses.
Treating excessive daytime sleepiness is complex. A first step may be to try to improve nighttime sleep, but often, in the absence of a suitable pharmacological treatment, the approach involves lessening the sedative effects of dopamine agonists during the day by reducing the dose or replacing them with L-Dopa. This requires a delicate balance in order to maintain control over motor symptoms in these patients. Unfortunately, excessive daytime sleepiness often fails to respond to these changes; in these cases it is thought to be linked to impairments to some arousal circuits in the brain. Modafinil is sometimes prescribed off-label to treat this symptom, but there is little evidence of the efficacy of this treatment in clinical trials.

More information is available on the France Parkinson association website https://www.franceparkinson.fr/somnolence-diurne-excessive/ (in French).

ABOUT THE THN102 TRIAL FOR PARKINSON'S DISEASE

The Phase II clinical trial examined the tolerability and efficacy of THN102 (modafinil/flecainide combination) in 75 Parkinson's disease patients with EDS characterized by a score of 14 or more (out of 24) on the Epworth Sleepiness Scale. The multicenter study was conducted in Europe and the United States.
The study was a double-blind, placebo-controlled, crossover trial with a one-week washout period between each successive two-week period of the following treatments in random order: THN102 200mg modafinil/2mg flecainide, THN102 200mg modafinil/18mg flecainide, or a placebo.
The primary endpoint of the trial was tolerability. The primary efficacy endpoint was excessive daytime sleepiness (EDS). Various exploratory parameters for efficacy and pharmacokinetics were also evaluated.

For further information about the Phase II multicenter trial: https://clinicaltrials.gov/ct2/show/NCT03624920

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[1] 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
[2] 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
[3] 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
[4] 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
[5] Adapted from the factsheet on excessive daytime sleepiness from French patient advocacy group France Parkinson

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

Contacts

THERANEXUS
Thierry Lambert
Chief Financial Officer
investisseurs@theranexus.fr

ACTUS finance & communication
Caroline Lesage
Investor Relations
+33 (0)1 53 67 36 79 / +33 (0)1 53 67 36 75
theranexus@actus.fr

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

ROONEYPARTNERS LLC
Kate Barrette
Media Relations US
+ 1 917.414.6962
kbarrette@rooneyco.com