PRESS RELEASE



CENTRAL NERVOUS SYSTEM DISORDERS



THERANEXUS TO PRESENT THE RESULTS OF THN102 FOR PARKINSON'S DISEASE AT THE 2020 INTERNATIONAL CONGRESS OF PARKINSON'S DISEASE AND MOVEMENT DISORDERS

The MDS Virtual Congress will take place from 12 to 16 September 2020.

Lyon, 30 July 2020 – 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, will present the Phase II results of its drug candidate THN102 for Parkinson's disease at the International Congress of Parkinson's Disease and Movement Disorders, due to take place from 12 to 16 September 2020.

The presentation, entitled "*THN102, an association of modafinil and low dose flecainide, in the treatment of excessive daytime sleepiness associated with Parkinson's Disease: a double-blind, placebo-controlled study,*" will be given by Professor Jean-Christophe Corvol from Pitié Salpêtrière Hospital and the Brain Institute, a Parkinson's disease specialist and principal investigator for the trial. THN102 was well tolerated by these often fragile patients. The reduction in daytime sleepiness, the primary efficacy endpoint, was successfully met, and THN102 also significantly increased the proportion of patients no longer presenting with excessive 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 excessive daytime sleepiness (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 with 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% versus 16.2% - p=0.05).

For **Professor Jean-Christophe Corvol**: "The positive results obtained by THN102 in this trial represent a major breakthrough in treating excessive daytime sleepiness in Parkinson's disease, which affects approximately 40% of patients. There is currently no treatment for this debilitating symptom, and the congress is an excellent opportunity to inform specialists of this new development."

"We would like to thank the organizers of this prestigious scientific congress for accepting our proposal to present the latest results of THN102 for Parkinson's disease. THN102 is currently the only treatment with demonstrated efficacy for this indication, which affects nearly 2 million people worldwide," explains **Franck Mouthon, Chairman and CEO of Theranexus.**

Seventy-five Parkinson's patients with debilitating excessive daytime sleepiness (EDS) were treated in this trial conducted in Europe and the United States. It was a double-blind, placebo-controlled, crossover trial with a one- to two-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.



ABOUT EXCESSIVE DAYTIME SLEEPINESS IN PARKINSON'S DISEASE¹

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 <u>https://www.franceparkinson.fr/somnolence-</u> <u>diurne-excessive/</u> (in French).

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: <u>www.theranexus.com</u>

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¹ Adapted from the factsheet on excessive daytime sleepiness from French patient advocacy group France Parkinson