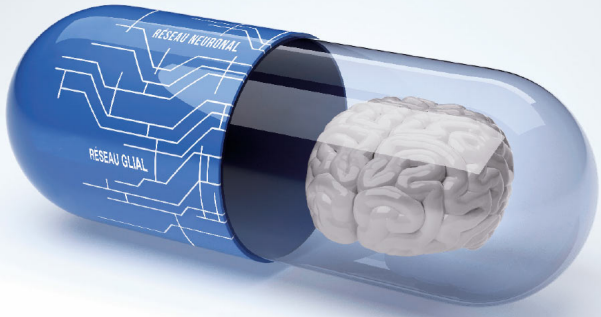
Theranexus

SHIFTING THE LINES AGAINST CENTRAL NERVOUS SYSTEM DISORDERS



THERANEXUS ANNOUNCES PRELIMINARY RESULTS OF PHASE II TRIAL OF THN102 ON NARCOLEPSY PATIENTS

Lyon, 27 February 2019 – 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 preliminary results of its Phase II trial in narcolepsy patients.

The trial entitled "Safety and Efficacy of THN102 on Sleepiness in Narcoleptic Patients" aimed to demonstrate THN102's superiority over the standard of care drug (modafinil) in a population of narcoleptic patients already taking modafinil, and who despite this treatment are experiencing residual disabling sleepiness. THN102's safety and tolerability profile has been deemed very satisfactory. However, the results do not indicate any difference in efficacy between THN102 (combination of modafinil and flecainide) and modafinil alone with respect to the trial's primary endpoint (Epworth Sleepiness Scale).

AN OVER-REPRESENTATION OF POORLY RESPONDING NARCOLEPTIC PATIENTS MAY ACCOUNT FOR THN102'S LACK OF DIFFERENCE IN EFFICACY FROM THE STANDARD OF CARE DRUG

Theranexus will continue to examine trial data with a view to evaluating the clinical profile of THN102. In particular, the company will be looking at the overly poor response to modafinil in some trial patients which prevented it from demonstrating THN102's superiority.

Chief Medical Officer of Theranexus, Dr Werner Rein stated, *"We are very grateful to the patients and investigators for their commitment to this clinical trial. We will be investigating the reasons why THN102 failed to demonstrate superiority over the standard of care drug in this population of narcoleptic patients experiencing significant residual sleepiness while taking modafinil. We believe that this patient group's low response capacity did not provide the necessary basis for achieving optimal activity from the combination."*

THN102 IN PARKINSON'S PATIENTS: UNTREATED PATIENTS WITH HIGH UNMET MEDICAL NEEDS CAUSED BY VIGILANCE AND ATTENTION IMPAIRMENTS

THN102 is being further developed to treat a triad of non-motor symptoms (sleepiness, attention and cognition disorders) in Parkinson's disease patients with no existing registered treatment. This combination, which addresses a significant unmet medical need in the disease, has a very high market value potential (estimated at more than $2 billion).

The ongoing Phase II trial aims to demonstrate the efficacy of THN102 on sleepiness, attention and cognition parameters in Parkinson's disease patients. THN102, unlike modafinil, had already demonstrated a substantial benefit on these parameters in the Phase Ib clinical trial of sleep deprivation in healthy subjects. In addition, unlike the Narcolepsy trial, the Phase II trial in Parkinson's patients compares THN102 to placebo in a patient population not receiving any treatment for these symptoms.

In parallel, Theranexus will continue to develop its two other active agents already in clinical trials, THN201 for neurocognitive disorders in Alzheimer's disease and THN101 for neuropathic pain, two indications for which unmet needs and market potential are very high (market > $3 billion for each). The company will also work to consolidate its platform, specifically through its collaboration with the Collège de France and the French Alternative Energies and Atomic Energy Commission (CEA) on the Neurolead project, in order to broaden and diversify its drug candidate portfolio.

Franck Mouthon, Chairman and CEO of Theranexus, concludes, *"We are maintaining our efforts to develop our various clinical assets, in particular by capitalizing on the value potential of THN102 in Parkinson's disease. Indeed, the triad of targeted non-motor symptoms without any registered treatment, as well as THN102's efficacy profile on these symptoms demonstrated in our Phase Ib trial, are key factors in ensuring this program's success".*

PORTFOLIO RECAP

THN102 - Parkinson's Disease

THN102 (modafinil/flecainide combination) is currently undergoing a Phase II clinical trial in Parkinson's disease patients. The trial's primary endpoint is safety of the drug candidate THN102 and secondary efficacy endpoints include an assessment of sleepiness, attention and cognition. The trial, enrolling 60 individuals, has already recruited more than a third of its patients, with all 20 planned sites open across Europe and the United States. Recruitment is expected to be completed by the end of the first half of 2019.

THN201 - Alzheimer's Disease

THN201 is a drug candidate for the treatment of neurocognitive disorders associated with Alzheimer's disease and moved into a phase Ib trial in September 2018. It contains a combination of donepezil, which acts on neuronal activity, and mefloquine, affecting glial cell activity. The recruitment of 150 healthy subjects at 8 sites in France is underway. Results will be made available by the close of 2019.

THN101 - Neuropathic pain

The THN101 Phase Ia safety, tolerability and pharmacokinetic study in patients with neuropathic pain is ongoing. The Phase II program is now defined. It will include 370 patients suffering from neuropathic pain of diabetic or post-Zosterian origin (following shingles) in 40 to 45 investigation sites in Europe. The main criterion will be based on a regular self-assessment of the patient's pain by patients themselves using a numerical scale.

Neurolead, a new platform enabling active agent screening in neuron-glia interactions

Theranexus was awarded a €6.2 million funding package under Bpifrance's Investments for the Future scheme, for the Neurolead program. This program, coordinated by Theranexus in collaboration with the Collège de France and the CEA, aims to design and industrialize a unique platform for the identification and characterization of drug candidates targeting neurological disorders. Using the latest innovations in neuroscience and AI tools, the platform will enable Theranexus to extend and systematize its therapeutic concept by enhancing its therapeutic application capabilities.

Next financial publication:
Monday April 29, 2019 (before market opening): 2018 annual financial results

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

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