



Theranexus

SHIFTING THE LINES AGAINST
CENTRAL NERVOUS SYSTEM
DISORDERS



PRESENTATION OF THE RESULTS OF THE PHASE Ib CLINICAL STUDY OF THN201 FOR ALZHEIMER'S DISEASE AT THE CLINICAL TRIALS ON ALZHEIMER'S DISEASE CONFERENCE (CTAD)

The conference will take place remotely from 4 to 7 November 2020.

Lyon, 4 November 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, is pleased to announce the presentation of the results of the Phase Ib study of THN201, "*Effects of THN201, a combination of donepezil and low dose mefloquine, on cognition and quantitative EEG in healthy subjects during a scopolamine challenge*," by Professor Régis Bordet, principal investigator for the THN201 study (University of Lille, Lille Teaching Hospital, Inserm), at the CTAD virtual conference from 4 to 7 November at 1pm CET.

THN201 is a proprietary combination of donepezil (the first-line treatment for managing Alzheimer's disease-related neurocognitive disorders) and mefloquine, an approved drug that has been repositioned at low doses as an agent for modulating the neuron-glia interface.

In January 2020, the results of the Phase Ib study revealed an extension of the pharmacological profile of the drug candidate THN201 compared to donepezil monotherapy. This extension is consistently reflected in greater speed of memory documented by the Cognitive Drug Research (CDR) computerized assessment¹ and increased gamma-band activity measured by quantified EEG analyses related to cognitive activity.² Data regarding the other measured pharmacological endpoints revealed that the profiles of THN201 and donepezil are similar.

"I am honored to present the results of the Phase Ib study of THN201 at CTAD. The convergence of positive effects of THN201 on high-level cognitive functions such as executive processes suggests potential for differentiation compared to donepezil, which would be worth further exploration in patients suffering from neurocognitive disorders," explains **Professor Régis Bordet**.

¹ (Lenz et al 2012)

² (Herrmann et al 2005, Palop et al 2016)

About the Phase Ib trial of THN 201 in Alzheimer's disease-related cognitive disorders

This multicenter study was conducted at 10 sites in Europe (ClinicalTrials.gov: NCT03698695). It included 152 healthy subjects. A total of 147 subjects completed the trial which was conducted as a double-blind, randomized, three parallel-group study (THN201, donepezil alone or placebo). Subjects were randomized to one of two treatment arms (or the placebo arm) and treated for 15 days. On day 1, participants received a 50 mg initial oral dose of mefloquine in the THN201 group or a corresponding placebo in the placebo and donepezil groups. THN201 repeated-dose treatments – mefloquine (10 mg) and donepezil (5 mg) or donepezil (5 mg) and placebo mefloquine, or placebo donepezil and placebo mefloquine – were administered orally once daily in the morning from D-1 to D-15. The tolerance and pharmacokinetics of THN201, compared with donepezil alone and the placebo, were evaluated repeatedly over the 15 days of treatment. On D-15, pharmacodynamic activity (analysis of cognitive activity measured by neuropsychological test batteries and of electrophysiological activity with quantitative EEG and event-related potentials) was assessed after measurable and reversible cognitive deficits were induced with scopolamine, a reference model for evaluating the pro-cognitive activities of drug candidates in healthy volunteers. Scopolamine is an inhibitor of the neurotransmission pathway stimulated by donepezil. It enables direct exploration of the pharmacological effect of donepezil and its possible modulation through the addition of mefloquine.

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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