PRESS RELEASE



SHIFTING THE LINES AGAINST CENTRAL NERVOUS SYSTEM DISORDERS



THERANEXUS ANNOUNCES INCLUSION OF LAST SUBJECT IN ITS PHASE IB TRIAL OF THN201

- This study compares the efficacy of THN201 with the standard-of-care drug in Alzheimer's disease associated neurocognitive disorders
 - Results are expected towards the end of 2019

Lyon, September 17, 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, has announced the inclusion of the last healthy subject in its Phase Ib trial comparing the pharmacological efficacy of its drug candidate THN201 with the standard-of-care treatment in Alzheimer's disease-related neurocognitive disorders.

A total of 152 healthy subjects were recruited at 10 sites in Europe. The trial was conducted as a double-blind, randomized, three arms, parallel study to evaluate the pro-cognitive activity, tolerance and pharmacokinetics of THN201 compared with the standard-of-care treatment alone or a placebo. THN201 has already demonstrated a preclinical pharmacological efficacy profile superior to the standard-of-care treatment in Alzheimer's disease and an excellent safety profile.

"We would like to thank Professor Régis Bordet, the Principal Investigator (University of Lille, Lille Teaching Hospital, Inserm), who conducted this trial with 9 other clinical trial sites in Europe and the volunteers who took part in the study. We look forward to obtaining the initial clinical efficacy data on THN201 because we are aware that treating neurocognitive disorders remains a major public health challenge today" concludes Franck Mouthon, CEO of Theranexus.

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

Alzheimer's disease (AD) is characterized by short-term memory loss, impairment of executive functions and temporal and spatial disorientation. Patients gradually lose their cognitive abilities and independence. Such neurocognitive disorders are particularly challenging, not only for patients but also for caregivers and families. Other diseases characterized by neurocognitive disorders (such as strokes or Parkinson's disease) currently represent a major unmet medical need and a significant economic burden. Health care costs associated with these neurocognitive disordersare estimated at over \$640 billion worldwide and predominantly driven by specialized nursing home costs. These costs continue to increase dramatically. Indeed, over 45 million people currently have neurocognitive disorders worldwide and this figure is expected to exceed 75 million by 2030.

This multicenter study was conducted at 10 sites in Europe. It included 152 healthy volunteers. Patients were randomized to one of the two possible treatment arms (THN201 or donepezil alone) or to the placebo arm and treated for 15 days. On day 1, participants received a 50 mg oral dose of mefloquine in the THN201 arm or a corresponding placebo in either the placebo or the donepezil arms. 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, pro-cognitive activity was measured with a scopolamine challenge, a standard model for assessing the pro-cognitive activities of drug candidates in healthy volunteers.



As a reminder, the Phase Ib trial is an integral part of the CX-COG project. It is conducted in partnership with Lille Teaching Hospital and Synerlab Développement, funded by the French government's "Fonds Unique Interministériel" (FUI), FUI AAP22, and approved by the Lyonbiopôle and Atlanpôle Biothérapies competitive clusters.

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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