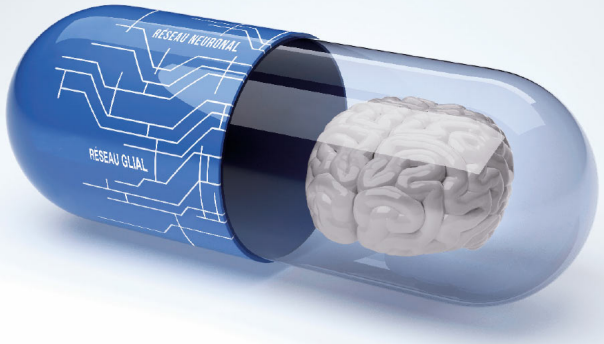
PRESS RELEASE

Theranexus

SHIFTING THE LINES AGAINST CENTRAL NERVOUS SYSTEM DISORDERS



THERANEXUS OBTAINS THE AUTHORIZATION TO START A PHASE Ib CLINICAL TRIAL WITH ITS DRUG CANDIDATE THN201 IN NEUROCOGNITIVE DISORDERS DUE TO ALZHEIMER'S DISEASE

A study aimed at demonstrating the clinical superiority of THN201 over a standard of care treatment for this severely debilitating symptom

Lyon, 26 September 2018 – 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, announces today it received the approval from French regulatory authorities to start a Phase Ib clinical trial with its drug candidate THN201.

This multicentre Phase Ib study will involve healthy volunteers and will be conducted in 8 French research centres. This phase Ibwill be a double-blind, randomised, parallel and placebo-controlled study aiming at evaluating the pro-cognitive activity, safety, and pharmacokinetics of THN201 compared with the standard of care drug donepezil, and a placebo.

The Phase Ib study forms an integral part of the Cx-COG project, which is financed by the French Government under the "Fonds Unique Interministeriel (FUI)", FUI AAP22, and supported by the competitiveness clusters "Lyonbiopôle" and "Atlanpôle Biotherapies". This project is being carried out in collaboration with Professor Régis Bordet, Co-ordinating Investigator, Lille University, Lille University Hospital Centre, Inserm, past-coordinator of the European IMI's PharmaCog project), as well as several other university hospital teams and the company Synerlab Développement for formulation, galenic innovation as well as for the production and control of clinical batches.

"*Improving the management of neurocognitive disorders, particularly in Alzheimer's disease, remains a major public health challenge. In this context of high patient expectations, THN201, stemming from Theranexus's technology, is a very promising drug candidate both for its mechanistic approach and its clear preclinical superiority in terms of efficacy over the standard of care treatment used for this indication."*explains Professor Régis Bordet, Neurologist - Clinical Pharmacologist at Lille's main teaching hospital.

"The regulatory clearance to conduct this study is a major step forward in the THN201 development programme.This study will produce the first data on the efficacy of THN201 in humans compared with the standard of care treatment, using a clinical study design that is a reference in terms of cognitive research especially with regards to prospective industrial partners. The results of this study will be available at the end of 2019" sums up Franck Mouthon, CEO of Theranexus.

About THN201 in cognitive disorders in Alzheimer's disease

Alzheimer's disease (AD) causes the slow degeneration of neurons which it is characterised by short-term memory loss, impairment of some bodily functions and can cause 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.

Today, many diseases characterised by neurocognitive disorders remain an economic burden and the cause of some significant unmet medical needs. Health costs associated with neurocognitive disorders estimated at more than $640 billion worldwide, predominantly driven by institutionalization, continue to increase dramatically. Today, it is estimated that more than 45 million people worldwide have neurocognitive disorders. A number expected to reach nearly 75 million by 2030

THN201 is a drug candidate for the treatment of cognitive disorders in Alzheimer's disease that is entering research Phase Ib The drug candidate THN201 is a combination of donepezil (which affects neuronal activity), and mefloquine (which affects glial cell activity). It has already demonstrated in preclinical studies a superior pharmacological efficacy than the reference treatment, as well as an excellent safety profile.

The associated multicentre study will be conducted in 8 French research centres. It will involve 150 healthy volunteers. Patients will be randomly selected and will receive one of the treatment arms (or its placebo comparator) and will be treated for 15 days. On day 1, participants will receive a 50 mg oral dose of mefloquine (THN201 arm) or a corresponding placebo (in the placebo and 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 - will be given orally once daily from D-1 to D-15 (in the morning). The tolerance and pharmacokinetics of THN201, compared with Donepezil alone and placebo, will be evaluated repeatedly over the 15 days of treatment. On D-15, pro-cognitive activity will be measured with a scopolamine screen, a reference model for evaluating the pro-cognitive activities of drug candidates in healthy volunteers.

About Synerlab Developpement

Created in 2012, Synerlab Développement is one of the six pharmaceutical sites of the european CDMO (Contract Developpement and Manufacturing Organization) Synerlab Group. Within a GMP authorized pharmaceutical establishment, the experienced multidisciplinary scientific team manages different technologies, using a multiple range of equipment to meet the challenges of the different stages of a drug development program. A specialist for pharmaceutical development of solid and liquid innovative products, Synerlab Développement is a recognized expert from first formulation trials up to pilot batch production scale, including manufacturing and quality control of clinical and commercial batches. Synerlab Développement manages complete development programs and handles custom-made galenical and analytical activities. Commited to flexibility and to high quality of services and products for its clients and partners, Synerlab Développement focus continuously on reaching project success and sustainable partnerships.

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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