Theranexus
SHIFTING THE LINES AGAINST CENTRAL NERVOUS SYSTEM DISORDERS

A NEW MILESTONE REACHED FOR THERANEXUS: INCLUSION OF LAST PATIENT IN PHASE II TRIAL FOR THN102 IN PARKINSON’S PATIENTS

• This trial conducted in Europe and the United States evaluates the tolerance and efficacy of THN102 on non-motor symptoms in Parkinson’s disease patients.

• Trial results expected in Q1 2020

Lyon, 24 September 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, recently achieved a new milestone by recruiting the last patient with Parkinson’s disease to its Phase II clinical trial which aims to evaluate the tolerance and efficacy of its drug candidate THN102 on non-motor symptoms of the disease.

Parkinson’s disease patients with excessive daytime sleepiness have been recruited across Europe and the United States. The trial’s primary endpoint is tolerance to the drug candidate THN102; the secondary efficacy endpoints concern a number of debilitating non-motor symptoms of the disease and include an assessment of sleepiness, attention and cognition. The study is a double-blind, placebo-controlled, crossover trial with a one-week washout period between each successive two-week period of the following treatments in random order: THN102 200mg modafinil/2mg flecainide, THN102 200mg modafinil/18mg flecainide, or a placebo.

For Professor Jean-Christophe Corvol of Pitie Salpetriere Hospital and the Brain and Spine Institute, “With the aging population and increasing numbers of elderly people, the number of patients affected by Parkinson’s disease will continue to rise. The non-motor symptoms targeted by THN102 for which there is no current treatment are a burden for patients themselves and their families, and also in socio-economic terms. The positive results achieved with THN102 in this trial are a tremendous step forward in treating these symptoms and improving the quality of life of patients.”

"We have achieved an important milestone with the completion of recruitment for our Phase II trial evaluating our drug candidate THN 102 in patients with Parkinson’s disease. The non-motor symptoms addressed by THN1021 affect 20 to 50% of patients and are particularly debilitating2 3. They are notably a risk factor for accidents4 5. There is currently no approved treatment for these symptoms. We are eagerly awaiting the results for THN102. These are due in Q1 2020 and would enable us to pursue our ambition of developing a high-value industrial partnership”, explains Franck Mouthon, CEO of Theranexus.

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3 Salawu F and Olokoba A. Excessive daytime sleepiness and unintended sleep episodes associated with Parkinson’s Disease - https://www.ncbi.nlm.nih.gov/pubmed/25829994
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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ABOUT THN102

THN102 (modafinil/flecainide combination) is currently undergoing Phase II clinical trials to treat a triad of non-motor symptoms (drowsiness, attention and cognitive disorders) in Parkinson’s disease patients, for whom no approved treatment is currently available. This triad, a major unmet medical need in the disease, has a very high market value potential (estimated at over $2 billion). The study protocol calls for the inclusion of 60 patients with Parkinson’s disease who suffer from EDS characterised by an Epworth Sleepiness Scale score of 14 (out of 24) or higher. The trial’s efficacy criteria compared to placebo include evaluations of drowsiness, alertness and cognition.

For further information about the Phase II multicenter trial: https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-004475-31/HU