



**Inclusion of the first patient in the phase II clinical study that aims to test THN102 in patients affected by narcolepsy.**

***This study aims to demonstrate the superior efficacy of THN102 compared to the reference treatment in narcolepsy patients.***

**Lyon, XX 2016** – Theranexus, a clinical-stage biopharmaceutical company, announced today that the first patient has been recruited in the study entitled “safety and efficacy of THN102 on sleepiness in narcolepsy patients” ([NCT02821715](#)), a phase II clinical study evaluating the efficacy and tolerance of THN102 in the treatment of excessive daytime sleepiness associated with narcolepsy in adult patients. This double-blind study will compare two different doses of THN102 with an active comparator, modafinil - the standard of care drug for treating sleepiness in narcolepsy patients. The protocol is being conducted according to a design referred to as cross-over: a study design in which each patient will receive all of the proposed treatments over successive treatment periods. The main objective of the study is to show a decrease in sleepiness as measured by the Epworth Sleepiness Scale (ESS) - the reference scale for measuring sleepiness in narcolepsy patients. This study, which is being financed in part by the French National Research Agency (ANR, project NarConX), will enroll in total 48 patients at three French centres, those being Montpellier Regional University Hospital (Professor Yves Dauvilliers – Principal investigator for the study), the Paris public hospital organisation APHP (Dr Isabelle Arnulf) and Lille Regional University Hospital (Dr Christelle Charley-Monaca).

Professor Yves Dauvilliers (Regional University Hospital in Montpellier, France) stated: “This new approach developed by Theranexus carries with it a real sense of hope for a better answer to the ever-weighty medical needs in narcolepsy. If we confirm in patients the data obtained in disease models as well as in healthy, sleep-deprived volunteers, then THN102 will represent an interesting therapeutic option for treating our patients once it is on the market. »

“Launching this phase II study with THN102 underscores our commitment at Theranexus to improving the life of patients suffering from narcolepsy,” declared Franck Mouthon, the President of Theranexus. “We see the completion of this study as a possibility to give a real-life demonstration of the ability of our technology to generate new and more effective drugs for patients suffering from neurological or psychiatric illnesses,” he added.



## **About narcolepsy**

Narcolepsy, also known as Gelineau's disease or Gelineau's syndrome, is a rare neurological disease. It is characterised by excessive, uncontrollable daytime sleepiness that is frequently associated with cataplexy (abrupt loss of muscle tone triggered by emotions), sleep paralysis, hypnagogic hallucinations, and changes in night sleep.

The disease generally appears in adolescence, both in men and women, but may also appear later (around age 35). In France, it is estimated that between 8,000 and 10,000 people are affected. More than 500,000 people are concerned worldwide. Between 50-70% of patients treated today with a wakefulness medication still suffer from sleepiness. Thus, it is essential to find a new, more effective treatment for this problem of hypersomnia which very strongly impacts the quality of life of these patients.

## **About THN102**

THN102 is the most advanced drug candidate in the Theranexus portfolio and is the first to represent a new class of innovative therapeutic combinations that associate a neural activity modulator, in this case modafinil (Modiodal®, Provigil®), with a glial connexin modulator which, in the case of THN102, is low-dose flecainide. THN102 has shown its superior efficacy compared to modafinil alone in *in vivo* narcolepsy models, (Duchêne et al. 2016), as well as in healthy, sleep-deprived volunteers (ESRS, September 2016). THN102 is now being studied in a Phase II clinical study in narcolepsy patients.

## **About Theranexus**

Founded in 2013, Theranexus is a biopharmaceutical company that originated from the French Alternative Energies and Atomic Energy Commission (CEA) - an institution that has been recently recognised as one of the most innovative research organisations in the world (according to the 'Top 25 Global Innovators' ranking by Reuters in March 2016). Theranexus designs and develops innovative combinations of CNS drugs with marketed medications that have been repositioned as glial connexin modulators. The clinical objective is to improve the efficacy and safety of established neurological and psychiatric treatments.

The scientific concept developed by Theranexus offers a unique opportunity to accelerate clinical development by using well-known, registered products and to limit the risk of treatment failure for high-potential neurological and psychiatric indications for which the authorised and established treatments present difficulties linked to tolerance, efficacy, or lifecycle management in terms of patent expiry. Theranexus is supported by investment institutions (Auriga Partners, Sofimac Partners, CEA Investissement, and Rhône-Alpes Création).

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