



## Theranexus Announces Issuance of European Patent Covering its Drug Candidate THN102 for Treatment of Narcolepsy and Parkinson's Disease

**Lyon, 11 January 2018** – Theranexus, an innovative biopharmaceutical company that focuses on the treatment of diseases of the central nervous system, today announces that it has obtained a European patent for its drug candidate THN102, primarily covering the treatment of narcolepsy and excessive daytime sleepiness associated with Parkinson's disease. The patent was issued to the French Alternative Energies and Atomic Energy Commission (CEA) on 3 January 2018 by the European Patent Office (EPO). CEA granted Theranexus a worldwide exclusive licence.

The patent, numbered EP3024458, names Franck Mouthon (CEO) and Mathieu Charvériat (CSO) as the inventors and is entitled "Use of flecainide as an anti-connexin agent and method for potentiating the effects of a psychotropic drug". It protects drug candidate THN102, which combines flecainide as an anti-connexin agent and modafinil as a psychotropic drug, and expires in 2034 (not including Supplementary Protection Certificate). The patent was obtained primarily on the basis of preclinical results published in the prestigious journal *Sleep* in 2016 that demonstrated the positive effects of THN102 on the two cardinal symptoms of narcolepsy: excessive daytime sleepiness and episodes of cataplexy.

**Franck Mouthon, Theranexus CEO, comments:** *"National patent offices have been swift to issue a patent with 'composition of matter' and 'therapeutic use' claims. This confirms once again the strong patentability of our therapeutic combination, as well as how groundbreaking it is. Our intellectual property investment plan is at the heart of our value creation strategy for THN102 in its various indications. We have protected our asset's value on the main and emerging pharmaceutical industry markets. Furthermore, at the end of 2017, we launched the regulatory activities required for us to start our new phase II clinical trial for THN102 in 2018. This phase II study will involve patients with Parkinson's disease<sup>1</sup> suffering from excessive daytime sleepiness. Its results are expected in the second quarter of 2019<sup>2</sup>. We will also have the results from the phase II study in narcoleptic<sup>3</sup> patients by the end of the third quarter of 2018. At Theranexus we remain ambitious that we can improve the treatment of sleepiness associated with narcolepsy and Parkinson's disease by positioning THN102 as the new gold standard for patients".*

Theranexus has already received widespread recognition for the quality of its innovation, with patents issued for THN102 in the United States, Japan and South Korea, and, more recently, in Israel, South Africa and Australia.

<sup>1</sup> Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's disease. It affects 1% of those above 65, almost three million people in the main countries targeted by the pharmaceutical industry (France, Germany, United Kingdom, Italy, Spain, United States and Japan). Thirty percent of these patients (around one million people) suffer from excessive daytime sleepiness (EDS), a symptom that increases the risk of accidents (traffic accidents, falls etc.) and therefore institutionalisation.

<sup>2</sup> The study will aim to demonstrate the safety and efficacy of THN102 compared to placebo in Parkinson's patients with excessive daytime sleepiness (EDS). It will be a double-blinded study (neither the patient nor the doctor will know which treatment is being assessed) and will compare two doses of THN102 (modafinil 200 mg + flecainide 2 or 18 mg) to a placebo in cross-over over three periods, meaning that each patient will be administered each of the three treatments at random during the three treatment periods, in about 60 patients. This equates to an estimated number of over 300,000 patients in the five main European markets (France, Germany, United Kingdom, Italy, Spain) and the United States.

<sup>3</sup> Narcolepsy is a rare disorder with an estimated global prevalence of 56 cases per 100,000 in the United States and 47 cases per 100,000 in the European Union. This study aims to demonstrate that THN102 has a better efficacy than the standard treatment (modafinil) in narcoleptic patients who experience residual excessive daytime sleepiness in spite of their treatment. It will involve a minimum of 42 patients, is double-blinded (neither the patient nor the doctor know which treatment is being assessed) and compares three treatments (modafinil 300 mg/day alone or in combination with two doses of flecainide, 3 and 27 mg/day) in cross-over over three periods. The recruitment period is to be completed by the end of the second quarter of 2018.

## THN102, a drug candidate for two indications: narcolepsy and Parkinson's disease

Theranexus has already demonstrated that drug candidate THN102 is superior in terms of efficacy across a number of key parameters in comparison to the standard treatment used alone, modafinil. These data were obtained in a clinical study conducted on sleep-deprived healthy volunteers. On the basis of these positive results, that imply a wide range of possible applications, THN102 is now positioned as an option for both narcoleptic patients and Parkinson's disease patients. In addition to presenting critical medical challenges to the daily lives of these patients, these two indications represent a significant opportunity for THN102 use. In the case of narcolepsy—an indication for which modafinil is the first line of treatment—the market is currently estimated at 2 billion dollars annually.

### ABOUT THERANEXUS

Theranexus is a biopharmaceutical company that emerged from the French Alternative Energies and Atomic Energy Commission (CEA) in 2013. It develops drug candidates for the treatment of central nervous system (CNS) 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). It now designs and develops the first drugs to act simultaneously on both these cell populations within the brain. 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-bourse.com](http://www.theranexus-bourse.com)



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