Theranexus announces issuance of US patent covering its drug candidate THN102 for treatment of narcolepsy and Parkinson's disease.

Lyon, 22 September 2017 – Theranexus, an innovative biopharmaceutical company that focuses on the treatment of diseases of the central nervous system, announced today that it has obtained US patent no. US 9,750,734. This patent was granted to the French Alternative Energies and Atomic Energy Commission (CEA) on 5 September 2017 by the United States Patent and Trademark Office. Theranexus benefits from a worldwide exclusive licence on this patent.

Titled "**Use of Flecainide as an anti-connexin agent and method for potentiating the effects of a psychotropic drug**", this patent protects Theranexus' drug candidate TNH102 that combines, on the one hand, flecainide as an anti-connexin agent and, on the other hand, modafinil as a psychotropic drug, until 2034 (not including Patent Term Extension).

"The United States is one of Theranexus' key target markets. This patent strengthens our IP portfolio for THN102 in the United States. This drug candidate is currently in a phase II clinical trial in patients with narcolepsy.[1]*. In parallel with narcolepsy, we are going to start a new phase II clinical trial in patients with Parkinson's disease*[2] *who suffer from excessive daytime sleepiness (EDS) at the end of 2017. Each of the two indications currently represents major unmet medical needs with, in the case of narcolepsy, an effect of the currently available psychostimulant perceived as insufficient by 90% of those who use it. Regarding Parkinson's disease, there is no treatment at all for EDS, a symptom that has a considerable impact on the quality of life of nearly 30% of Parkinson's patients,"* declares Franck Mouthon, Theranexus CEO.

This new patent US 9,750,734 also protects, in the US, methods of treatment for the use of the drug candidate THN102 to treat patients suffering from both diseases (Narcolepsy and Parkinson's disease).

This protection is an addition to patents previously granted or in the process of being granted for the same family of treatments in other regions such as Europe, Australia, Israel, South Africa, South Korea and Japan.

This patent was obtained mainly on the basis of preclinical results published in the prestigious journal *Sleep* and showing THN102's effects on the two cardinal symptoms of narcolepsy, excessive daytime sleepiness and episodes of cataplexy.

[1] Narcolepsy is a rare disease with an estimated global prevalence of around 56 cases per 100,000 in the United States and 47 cases per 100,000 in the EU. These prevalence rates translate into an estimated 300,000 patients in the 5 main European markets (France, Germany, the UK, Italy, Spain) and the US.

[2] Parkinson's disease is the second most common neurodegenerative disorder after Alzheimer's. It affects 1% of those above 65, which translates to nearly 3 million people across the pharmaceutical industry's main target countries (France, Germany, the UK, Italy, Spain, the US, and Japan). 30% of these patients, or nearly 1 million people, suffer from EDS and with it an increased risk of accidents (circulation, falls, etc.) and therefore institutionalisation.

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

THN102 is a drug candidate which efficacy has already been demonstrated across a number of parameters in comparison to the standard of care treatment used alone, modafinil. These data were obtained in a clinical study conducted in sleep-deprived healthy volunteers. On the basis of these positive results that open a wide range of applications, THN102 appears as a possible future valuable options for patients with narcolepsy as well as those with Parkinson's disease. THN102 is currently being investigated for the first time in a phase II clinical trial in narcoleptic patients[3] with results expected in the third quarter of 2018. A second phase II trial in Parkinson's disease patients[4] with EDS should also be launched by the end of 2017 with results expected in the first half of 2019.

In addition to medical issues that are critical to the daily lives of these patients, these two indications represent an opportunity for the use of THN102, with in the case of narcolepsy, an indication for which modafinil is the first line of treatment, is a market size currently estimated at 2 billion dollars annually.

About Theranexus
Theranexus is a clinical-stage biopharmaceutical company founded in 2013 and spun-out from the French Atomic Energy Commission (CEA). Capitalizing on the prominent role nonneuronal cells play in neuron activity, Theranexus designs and develops ground-breaking drug candidates that act simultaneously on both cell types within the brain. Its clinical objective is to provide innovative and effective therapeutic solutions for the treatment of neurological disorders.
By choosing to apply its concept through the combination of registred drugs, Theranexus is able to drastically shorten development time and considerably increase the chances of success of its R&D process.
Theranexus has financial backing from Auriga Partners, Sofimac Partners, CEA Investissement, and Kreaxi. - http://www.theranexus.com

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[3] This study aims to show THN102's superiority to benchmark treatment (modafinil) in narcoleptic patients who have, despite treatment, excessive daytime sleepiness. This is a double-blind study (neither the patient nor the doctor knows which treatment is being evaluated) and compares three treatments (modafinil 300 mg/day alone or combined with two doses of flecainide, 3 and 27 mg/day) in crossover in three periods: each patient receives, randomly and for three periods each of 2 weeks, each of the three treatments. Currently, 20 patients have been included, out of a required total of 42. The end of recruitment is planned for the end of the second quarter of 2018.
[4] This study aims to demonstrate the safety and efficacy of THN102, in comparison with a placebo in Parkinson's patients with Excessive Daytime Sleepiness (EDS). This will be a double-blind study (neither the patient nor the doctor knows which treatment is being evaluated) comparing two doses THN102 (modafinil 200 mg + flecainide 2 or 18 mg) with a placebo, in crossover in three periods, conducted on around 60 patients.