

Theranexus reaches its primary endpoint in the proof of concept trial of THN102 in Excessive Daytime Sleepiness (EDS)

A major result for the company that validates for the first time in man its approach of combining a CNS drug with a glial connexin modulator.

Lyon, May 17th 2016 –Theranexus, a clinical-stage biopharmaceutical company, announced today top-line results from its proof of concept clinical trial in Excessive Daytime Sleepiness (EDS) induced by sleep deprivation in healthy volunteers. Those results show a beneficial effect of THN102 (combination of modafinil and flecainide, repurposed at low dose as glial connexin modulator) on outcomes measuring vigilance and cognition throughout the sleep deprivation and when compared to the standard of care modafinil.

The study was a double-blind, randomised, placebo and active comparator (modafinil) controlled, incomplete cross-over study in 20 healthy volunteers undergoing sleep deprivation. This study was led by Dr. Fabien Sauvet, from the French Armed Medical Research Institute (IRBA) at the Percy military hospital, Clamart – France. Treatment units were produced and released by the Central Pharmacy of Military Health Service. The study was funded by the French Defense Procurement and Technology Agency (DGA) under the RAPID program which aims at funding innovations having both civil and military possible applications.

THN102-treated volunteers showed a statistically significant improvement in their vigilance levels – the primary endpoint of the study - vs modafinil alone. Secondary endpoints assessing cognition were consistent with this effect. Detailed results will be published and presented at upcoming conferences, and they reinforce the interest of THN102 for the treatment of Excessive Daytime Sleepiness, a debilitating symptom affecting a number of patients with CNS disorders such as narcolepsy or Parkinson’s disease.

“Reaching the primary endpoint of efficacy vs. modafinil on the levels of vigilance provides further evidence of the synergistic effects of modafinil with flecainide low dose,” said Dr. Mathieu Charvériat, CSO of Theranexus. *“Results from the secondary endpoints were also very promising. The THN102 treated group experienced fewer adverse events compared with the modafinil treated group as well. This is really exciting as we see a strong evidence for the translation in man of Theranexus’ concept of associating a glial modulator with a CNS drug to increase the efficacy of the latter.”*

“We are grateful to the staff from the IRBA for the excellent job they have done in this study which would not have been possible without the support of the French Ministry of Defense,” stated Franck Mouthon, CEO of Theranexus. *“The efficacy of THN102 in this proof of concept trial is highly encouraging for the patients suffering from Excessive Daytime Sleepiness. This reinforces our confidence into the recently started phase 2 trial in narcolepsy which outcome should be known in the second half of 2017. ”*

This first evidence of efficacy with THN102 supports the translation of Theranexus' concept in man

Such evidence illustrates as well the ability of Theranexus' science to successfully move from the bench, with the results recently published in the peer-reviewed journal *Sleep*, to the bedside.

Franck Mouthon added: *"These results are a first validation in man of Theranexus' technology, based on the key role of glial connexins to improve the safety and efficacy of CNS drugs. Beyond the THN102 project, we see there a validation of our strategy that relies on the use of marketed drugs and allowed us to reach this key milestone within 3 years from the inception of the company."*

About Excessive Daytime Sleepiness (EDS)

Excessive daytime sleepiness (EDS) is characterized the inability to stay alert and awake during the major waking episodes of the day, resulting in unintended lapses into sleep. EDS can be considered as a debilitating broad condition encompassing several sleep disorders where increased sleep is a symptom, or as a symptom of another underlying disorder like narcolepsy, Parkinson's disease or Obstructive Sleep Apnea (OSA).

About Theranexus

Founded in 2013, Theranexus is a biopharmaceutical company formed from a spin-off of CEA - an institution recently recognized as the most innovative research body in the world (as per ranking in Reuters' Top 25 Global Innovators). Theranexus discovers and develops combinations between CNS drugs and marketed drugs repurposed as glial connexin modulators, with the objective of improving the effectiveness and tolerance of established neurological and psychiatric treatments.

The Theranexus science offers a unique opportunity: accelerated clinical development with a lower risk of project failure in high potential CNS indications where authorized and established treatments have problems either with tolerance and effectiveness, or with life-cycle management in relation to patent expiries. Theranexus is VC-backed (Auriga Partners, Emergence Innovations (Sofimac Partners), CEA Investissement and Rhône-Alpes Création).

www.theranexus.com

About Military Health Service (Service de Santé des Armées)

The French Armed Medical Research Institute (IRBA), the Percy military hospital, and the Central Pharmacy are entities of the Military Health Service. This Institution is turned towards dual developments, based on the collaborations between civil teams and Armed forces through high level scientific and technological platforms and experimental models.

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