



Theranexus and its partners receive support from the FUI (French Inter-ministry Fund) for their project, Cx-COG

An ambitious project of US\$ 3.6 million on the clinical validation of the efficacy of product THN201 in the treatment of neurocognitive impairment caused by Alzheimer's disease.

Lyon, 20th of September 2016 – Theranexus, a clinical-stage biopharmaceutical company, has announced today that it has received funding from the FUI (French Inter-ministry Fund) for its project CX-COG (FUI AAP22) which has been approved by the competitiveness clusters Lyonbiopôle and Atlanpôle Biothérapies. This project, which will be carried out in collaboration with the team of Prof. Régis Bordet (Lille University, Lille University Hospital, Inserm) and the company Synerlab, concerns the pharmaceutical formulation development and clinical validation of the efficacy of product THN201 in the treatment of neurocognitive impairment particularly associated with Alzheimer's disease.

The goal of the project launched by Theranexus is to demonstrate the clinical performance of an innovative proprietary combination of donepezil, a reference treatment for neurocognitive impairment, and an existing medication that improves the efficacy of donepezil fivefold.

The outcome sought from this development is to rapidly strengthen the therapeutic arsenal by inducing a 12 to 18 month delay in cognitive decline and placement in a care facility among patients affected by neurocognitive impairment. The currently available therapeutic arsenal against neurocognitive impairment that is mostly associated with Alzheimer's disease is only able to modestly slow the evolution of impairment towards more severe forms.

"We are delighted that our project was chosen by the FUI, a leading source of public funding for innovation in France. Furthermore, we are particularly grateful to the competitiveness clusters Lyonbiopôle and Atlanpôle Biothérapies, the Regional Directorate for companies, competition, consumption, work and employment (Direccte) of the Auvergne-Rhône-Alpes region, and the French Public Investment Bank (BPI), which provided us with the unfailing step-by-step support and assistance that enabled us to reach this point. Thanks to this critical backing, to the contributions from the Auvergne-Rhône-Alpes region, the Centre-Val de Loire region, and the city of Lyon, as well as the commitment of our partners in this project, we will be able to pursue our investment and accelerate the development of THN201 for the treatment of neurocognitive impairment," rejoiced Franck Mouthon, the President of Theranexus.

Project CX-COG, which is being coordinated by Theranexus, covers the design and development of combinations of existing medications that have been proven to improve the efficacy of certain neurological and psychiatric treatments. It is being carried out in partnership with the company Synerlab Développement, which is specialised in the development of original pharmaceutical formulations, and with the team of Prof. Régis Bordet (Joint research unit [UMR-S] 1171 & Clinical Investigation Centre [CIC] of Lille), who is an internationally recognised expert in the clinical evaluation of neurocognitive impairment and new therapies.

"We are happy to receive this financing which will allow us to apply our expertise in pharmaceutical formulations in new ways. When we combine our capacity for innovation with the innovation proposed by Theranexus, we should be able to offer patients affected by neurocognitive impairment a more effective solution that is better adapted to the care needs of their disease," declared Emmanuelle Brun, the CEO Synerlab Développement.



"The Theranexus project is an ambitious project that we are following very closely," explained Prof. Régis Bordet ((Joint research unit [UMR-S] 1171 & Clinical Investigation Centre [CIC] of Lille). We are particularly interested in participating in the reinforcement of this concept, which proposes combining a glial connexin modulator with a CNS drug in order to improve the efficacy and safety, particularly through the key step of the project, which is proving the concept in humans and which will draw on the process and know-how that resulted from the European project Pharmacog (IMI). This original approach offered by Theranexus is a source of new hope for answering very pressing medical needs in the treatment of neurocognitive impairment."

The partners of the CxCOG consortium now plan to initiate at the earliest possible time the foreseen characterisation work in *in vivo* models and, in healthy subjects, of the tolerance and pharmacokinetic parameters of THN201. Work towards developing an innovative formulation for the product will also be carried out alongside these activities. Once accomplished, these tasks should make it possible to launch a clinical proof-of-concept study within 15 months. The study itself should last 15 months as well.

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). Theranexus designs and develops combinations of CNS drugs with marketed medications that have been repositioned as glial connexin modulators, with the goal of improving the efficacy and safety of established neurological and psychiatric treatments.

The science developed by Theranexus offers a unique opportunity to accelerate clinical development, limit the risk of treatment failure for high-potential neurological and psychiatric indications for which the authorized 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).

<http://www.theranexus.com>

About Synerlab Développement

Created in 2012, Synerlab Développement is one of the six units of the Synerlab group. As a pharmaceutical establishment possessing the necessary certification for producing medications, this development centre currently has 35 collaborators. Synerlab Développement is an experienced scientific team that has mastered several technologies and is also endowed with a wide range of equipment that is appropriate for the various stages in the process of developing pharmaceutical formulations of medications. Synerlab Développement specialises in the pharmaceutical development of solid, oral forms and has positioned itself as an expert in the first stages of formulation all the way through to pilot-scale production, including the production of clinical study batches and commercial batches. The company can also adapt itself to specific needs that come up during research and development projects on analytical and pharmaceutical formulation activities. The company's strength lies in its concern for constantly improving and performing well in the areas of responsiveness, flexibility, quality service and products.

<http://www.synerlab.com/synerdev/accueil>

Press contacts

ComCorp

Adélaïde Manester

+33 1 58 18 32 44 - +33 6 70 45 74 37

amanester@comcorp.fr