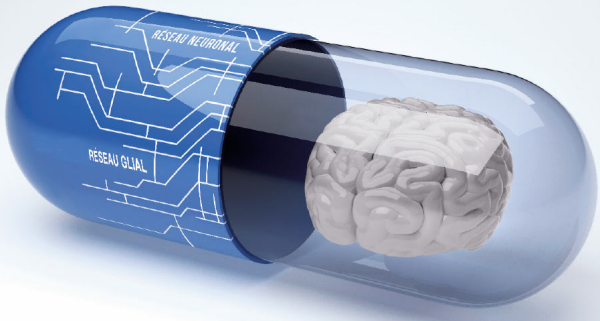
PRESS RELEASE

Theranexus

SHIFTING THE LINES AGAINST CENTRAL NERVOUS SYSTEM DISORDERS



THERANEXUS SECURES €3.4 M LOAN UNDER THE FRENCH STATE GUARANTEE SCHEME (PGE) AND PROVIDES AN UPDATE ON ITS DEVELOPMENTS

€6.5 M non-dilutive funding including PGE in Q2 2020

Progress report on THN102 and BBDF-101 programs

Lyon, 24 June 2020 – Theranexus, a biopharmaceutical company innovating in the treatment of neurological diseases and pioneer in the development of drug candidates modulating the interaction between neurons and glial cells, is pleased to announce the signing of a €3.4 million non-dilutive loan agreement and provides an update on its clinical developments.

Approximately €6.5 M in non-dilutive funding during Q2 2020

The company recently secured a loan for €3.4 M under the French PGE State Guarantee Scheme from a consortium consisting of long-standing partner banks and Bpifrance. Under the loan agreement no repayment is required for 12 months and installments are then spread over a maximum 5-year period.

In addition, Theranexus benefited from an accelerated full refund of the 2019 Research Tax Credit (CIR) for a sum of €2 M in May 2020. Lastly, the company received from Bpifrance the first part of the funding (€1 M) for its Neurolead R&D platform, developed in partnership with the Collège de France and the French Alternative Energies and Atomic Energy Commission (CEA) and financed under the Structuring Research and Development Projects for Competitiveness scheme (PSPC[1]) initiative operated by Bpifrance. The company is set to receive a further €3 M spread over the next three years in connection with the project.

As a reminder, the company's cash amounted to €7.8 M[2] at 31 March 2020 and did not include any of the above-listed payments.

Progress report on THN102 and BBDF-101 programs

Drug candidate THN102 – Excessive daytime sleepiness (EDS) in Parkinson's disease

The positive results from the Phase II clinical trial[3] establish THN102 as the first potential treatment for excessive daytime sleepiness (EDS) in patients with Parkinson's disease. Moreover, the absence of residual sleepiness in more than 25% of patients after treatment with THN102 promises a high level of medical service rendered.

[1] https://www.theranexus.com/images/pdf/Theranexus_PR_PSPC_BPI_FINAL_20190129_VDEF.pdf
[2] https://www.theranexus.com/images/pdf/Theranexus_PR_2019_Full_Year_Results_2019_EN.pdf
[3] https://www.theranexus.com/images/pdf/Theranexus_PR_THN102_Parkinson_EN.pdf

According to a recent study by the leading consultancy firm Clarivate Analytics in June 2020, 40% of Parkinson's patients suffer from EDS in the absence of available treatment. More than half of them suffer from EDS that is sufficiently debilitating, both in terms of quality of life but also overall progression of the disease, to require specific treatment of the symptom which would therefore potentially be treatable with THN102. According to estimations by Clarivate Analytics, on the basis of its efficacy and safety profile established during Phase II trials, THN102 could achieve sales in excess of a billion dollars with a treatment price of more than 20,000 dollars in the United States and 5,000 dollars on average in Europe.

As announced previously, one objective for Theranexus is to join forces with a larger pharmaceutical player to capitalize on the positive results of this Phase II trial. This will allow Theranexus to be in a position to ensure the later stage clinical development of the drug candidate through to its approval and commercialization. This partnership is expected to be launched by the end of 2020. In this context, initial discussions with prospective partners confirmed the interest in THN102 of some of them and the team is confident this goal is achievable.

Drug candidate BBDF-101 for Batten disease, a rare orphan pediatric disorder of the nervous system

As a reminder, in December 2019, Theranexus and the Beyond Batten Disease Foundation (BBDF) announced an exclusive, global license agreement for the drug candidate BBDF-101 which covers the clinical development of the drug candidate BBFD-101 pending approval and its commercial use.

BBDF-101 is a drug candidate combining trehalose and miglustat, two active ingredients each with its own specific activity of interest for the disease as well as a synergistic effect.

The safety profile of each of the two compounds is well known and highly favorable: miglustat is a drug already approved in another rare disease and trehalose is a common excipient (notably for IV solutions). As the clinical program involves treating pediatric patients over a long period (24 months), the Food and Drug Administration[4] requested that Theranexus confirm without delay the preclinical safety of trehalose over a long exposure time to supplement the data already available. In light of the frequent use of trehalose – notably in IV solutions – and of miglustat, the company is very confident of the outcome of the research. The preclinical phase was initially planned in parallel with the clinical program, but will be brought forward to allow the program launch to proceed in the second half of 2021. Moreover, talks with the FDA confirmed that, if successful, the planned clinical development program would lead directly to product approval. In addition, "Orphan Drug" status is expected to be granted by the FDA and EMA[5] in the coming weeks.

Franck Mouthon, Chairman, CEO and co-founder of Theranexus, concludes: "*I would like to thank the French government, as well as Bpifrance and our banking partners for their support and efforts in helping us to consolidate our cash position. All the non-dilutive funding from the first half of the year, amounting to close to €6.5 M, will help sustain the development of our business activities and strengthen our position in discussions with an industrial partner for THN102, which we aim to finalize by the end of 2020. This agreement will boost the company's value and growth prospects.*"

[4] U.S. Food and Drug Administration (FDA)
[5] European Medicines Agency (EMA)

About THN102 for Parkinson's disease

THN102 met the primary efficacy endpoint of the Phase II clinical trial and significantly reduced EDS in Parkinson's patients with severe excessive daytime sleepiness (EDS of 16.5 on average) scored on the Epworth Sleepiness Scale (ESS). The ESS score improved by 3.9 points in patients after treatment with THN102-200/2. This improvement is highly significant (p=0.01) compared with that achieved by the placebo (2.4 points). Moreover, the proportion of patients no longer presenting with excessive daytime sleepiness for the duration of the treatment was considerably higher with THN102-200/2 than in the placebo group (p=0.05). The trial also demonstrated the excellent tolerability of THN102 and the absence of a negative impact on the disease's other symptoms.

Roughly 40% of patients suffering from Parkinson's disease are affected by excessive daytime sleepiness. The symptom is recognized by practitioners as a significant medical need[6] and associated with a considerably increased accident risk[7].

About BBDF 101 for Batten disease

The juvenile form of Batten disease, also known as Spielmeyer-Vogt or CLN3 disease, is a rare, fatal, genetic disorder of the nervous system for which there is no treatment. It belongs to a group of disorders referred to as neuronal ceroid lipofuscinoses (NCLs). If successful, the clinical development program securing product approval will be launched in 2021. It will include efficacy measurements comparing the development of various symptoms to natural disease progression documented on the basis of patient cohorts already followed up as well as the safety and pharmacokinetic profile of BBDF-101. The program will include an adolescent/adult cohort and a pediatric cohort:

- The trial will begin with the enrollment of an adolescent/adult cohort of six patients who will all be administered the drug BBDF-101 in escalating doses, with tolerability and pharmacokinetics established over 5 months. These patients will continue to be administered BBDF-101 throughout the trial and followed up for safety.
- Once measurements of pharmacokinetics and tolerability have been performed for the adolescent/adult cohort, a pediatric cohort of 30 patients will be enrolled and undergo regular measurements to assess disease progression (vision, cognition, motor symptoms, etc.) over a period of two years.

At the end of the trial, patients' data will be compared to natural disease progression as measured within cohorts already followed up by American and European academic teams.

Next financial publication:

Thursday 9 July 2020 (before market opening): Cash position as of 30 June 2020

Theranexus is a clinical-stage biopharmaceutical company that emerged from the French Alternative Energies and Atomic Energy Commission (CEA) in 2013. It develops drug candidates for the treatment of nervous system 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). The company is a pioneer in the design and development of drug candidates affecting the interaction between neurons and glial cells. 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.com

[6] Survey conducted with 23 experts in Europe and the United States
[7] Spindler et al., 2013

More information at
http://www.theranexus.com
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