PRESS RELEASE

Theranexus

SHIFTING THE LINES AGAINST CENTRAL NERVOUS SYSTEM DISORDERS

BEYOND BATTEN DISEASE FOUNDATION

THE FOOD AND DRUG ADMINISTRATION (FDA) ISSUES A FAVORABLE OPINION ON THE PRECLINICAL DEVELOPMENT PLAN SUBMITTED BY THERANEXUS AND BBDF

Lyon, 19 November 2020 – Theranexus, a biopharmaceutical company innovating in the treatment of neurological diseases, and the Beyond Batten Disease Foundation (BBDF) announced securement of the favorable opinion of the Food and Drug Administration (FDA) for the continuation of an optimized preclinical development plan relating to BBDF-101 in a bid to achieve IND status and begin clinical trials of BBDF-101 with a long exposure time (24 months) pending approval.

This binding opinion was issued by the FDA in writing in a type C meeting, thus approving Theranexus' proposals to continue the preclinical development of BBDF-101 previously initiated by the Company.

"*We would like to thank the FDA for its interest and the quality of regular contacts regarding development of the drug candidate BBDF-101 for Batten disease. We are delighted about this latest positive meeting with the FDA. The result is the continuation of an optimized preclinical development plan to initiate clinical trials in patients with Batten disease starting in 2021"* explains **Franck Mouthon, Chairman and CEO of Theranexus.**

"We are very pleased by the FDA's recent approval of the preclinical development plan for BBDF-101, as this paves the way for the initiation of clinical trials which we all hope will deliver a therapeutic response for children and young adults with this terrible disease" explains **Craig Benson, Chair of the BBDF Board of Directors**

In late 2019, Theranexus and BBDF signed an agreement granting Theranexus an exclusive, global license agreement for the development and commercial use of drug candidate BBDF-101 for juvenile Batten disease. Batten disease belongs to a group of disorders referred to as neuronal ceroid lipofuscinoses (NCLs). BBDF funded research aimed at identifying and validating BBDF-101, a proprietary combination of drugs based on the synergistic effect of two active ingredients, like the other Theranexus drug candidates already in clinical development.

Theranexus and BBDF have since been awarded U.S. Orphan Drug Designation and European Orphan Medicinal Product designation as well as U.S. Rare Pediatric Disease status.

ABOUT THERANEXUS

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).

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