



THERANEXUS PUBLISHES ITS 2022 FULL-YEAR RESULTS AND PRESENTS AN UPDATE ON ITS PROGRAMS

Lyon, France – 12 April 2023 – 6pm CEST – Theranexus, a biopharmaceutical company innovating in the treatment of rare neurological diseases and pioneer in the development of drug candidates modulating the interaction between neurons and glial cells, today publishes its results for the year ending 31 December 2022 and its cash position as of 31 March 2023, and presents an update on its programs.

"In 2022 the company opted to focus its business on rare neurological diseases, a market segment in which we operate through the development of Batten-1 for Batten disease. The initial positive results of the Phase I/II clinical trial of Batten-1, with the demonstration of a good tolerability, safety and pharmacokinetic profile, enable us to plan the Phase III registration study involving a pediatric cohort during 2023. The company has also formed strategic alliances with leading partners to identify novel targets and advanced therapy drug candidates. These growth opportunities enable Theranexus to strengthen its market position in rare neurological diseases," **Theranexus CEO, Mathieu Charvériat explains.**

2022 annual financial results (French GAAP)

€K	2022	2021
Turnover	-	-
Operating income	1,246	25
Other purchases and external charges	3,967	5,591
Wages and social security charges	3,165	2,689
Amortization and depreciation of fixed assets	332	1,204
Other operating expenses	39	53
Operating expenses	7,503	9,537
Net operating income/(expenses)	(6,257)	(9,512)
Net financial income/(expense)	(158)	(396)
Non-recurring expenses	(771)	-
Income tax	619	1,758
Net income/(expense)	(6,567)	(8,150)

The 2022 full-year results were approved by the company's Board of Directors on 12 April 2023 and were the subject of a report by the company's Statutory Auditors.

In 2022, operating income particularly benefited from grants awarded in relation to the Neurolead research platform, totaling €1,246 K.

Other purchases and external charges declined in 2022 (€3,967 K) compared to 2021 (€5,591 K) owing to substantial regulatory preclinical expenses incurred for Batten-1 in 2021, which were partly offset by the new Phase I/II clinical trial for Batten disease in 2022.



Wages and social security charges recorded a moderate increase with €3,165 K in 2022 compared to €2,689 K in 2021.

Amortization and depreciation costs for 2022 were €332 K. Non-recurring expenses stand at -€771 K due to the removal of legacy patents. Write-back on depreciation of fixed assets for €771 K was also recorded.

Income tax stands at €619 K in 2022 compared to €1,758 K in 2021. This reduction is mainly explained by the fact that the Company's clinical expenses for 2022 related to its Phase I/II Batten-1 trial in the U.S. and are therefore not eligible for the Research Tax Credit (CIR). Conversely, in 2021, the Company incurred significant expenses eligible for CIR, most notably regulatory preclinical expenses for its Batten disease candidate development.

Cash position as of 31 March 2023

On 31 March 2023, total available funds stood at €7.3 M in line with the company's forecasts; this was achieved through careful management and secures at least 12 months' visibility.

Highlights of 2022 and Q1 2023

- **Strategic focus on rare neurological diseases and new milestone in company organization**

In April 2022, Theranexus opted to focus on rare neurological diseases to concentrate R&D on its Batten-1 drug candidate for Batten disease and identification of novel advanced therapy active substances. In January 2023, to drive forward these next phases of its development, changes were made to the company's organization with the appointment of Mathieu Charvériat as CEO and Franck Mouthon as Executive Chairman.

Following its new strategic direction, the Company gave several scientific and business presentations in 2022 and early 2023 such as at the fUSbrain conference (June 2022), the BIO business convention (June 2022), the Federation of European Neurosciences Societies (FENS) Forum (July 2022), the Batten Disease Support and Research Association (BDSRA) conference (July 2022) and the J.P. Morgan Healthcare Conference (January 2023).

New advances to the Batten-1 program

In 2022, in partnership with BBDF, Theranexus pursued the development of its Batten-1 drug candidate in juvenile Batten disease, for which it holds an exclusive, global license for development and commercial use. In early 2023, Theranexus and BBDF achieved an important milestone with the announcement of positive results in their Batten-1 program in the Phase I/II clinical trial, with the demonstration of good patient safety and tolerability and a pharmacokinetic profile in line with expectations. These results enable Theranexus and the Foundation to prepare for the Phase III trial paving the way to Batten-1 approval. The partners plan to initiate this clinical trial involving a pediatric cohort by the end of 2023.

During the past year, Theranexus and its scientific partners Marco Sardiello of Baylor College of Medicine (Houston, USA) and Emyr Lloyd-Evans of Cardiff University (UK) presented their research at two major conferences for the community of researchers specialized in lysosomal diseases – Translational Research Conference for the Management of NCLS (Chicago, USA – November 2022) and WORLDSymposium (Orlando, USA – February 2023). During these events, for the first time the partners shared data demonstrating the fundamental role of glycosphingolipid accumulation in the pathophysiology of the disease, as well as the potent effect of miglustat on reducing this accumulation and resulting neuronal death.



- **New strategic alliances for identifying novel targets and advanced therapy drug candidates in rare neurological diseases**

In Q4 2022, Theranexus signed a strategic alliance with **Inserm Transfert**, the value creation subsidiary of the French National Institute of Health and Medical Research (Inserm). With this new agreement, Theranexus benefits from preferential early access to Inserm research for identifying and characterizing novel targets and RNA or antisense oligonucleotide candidates to treat patients with rare neurological diseases.

In a similar vein, in early 2023 Theranexus and its partners **Inria, Claude Bernard Lyon 1 University and Hospices Civils de Lyon** announced the launch of a joint public-private research project team called AlstroSight to develop innovative digital methods in a bid to identify novel targets and drug candidates designed to treat brain diseases.

These alliances are perfectly in line with Theranexus' development strategy and fuel the company's strong ambition to consolidate its positioning and portfolio in rare neurological diseases.

About Theranexus

Theranexus is an innovative biopharmaceutical company that emerged from the French Alternative Energies and Atomic Energy Commission (CEA). It specializes in the treatment of central nervous system disorders and is a pioneer in the development of drug candidates targeting both neurons and glial cells.

The company has a unique platform for the identification and characterization of advanced therapy drug candidates targeting rare neurological disorders and an initial drug candidate in clinical development for Batten disease.

Theranexus is listed on the Euronext Growth market in Paris (FR0013286259- ALTHX).

More information at

<http://www.theranexus.com>

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