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GENKYOTEX REPORTS PROGRESS OF SETANAXIB PHASE 2 INVESTIGATOR INITIATED TRIALS

- ***Phase 2 DKD trial funded by JDRF to expand in Europe and New Zealand***
- ***13 patients have completed full 48-week treatment in DKD trial; no safety signals identified***
- ***Phase 2 IPF trial funded by NIH; poised to initiate patient enrollment following recently received FDA and IRB approvals***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX) a biopharmaceutical company and the leader in NOX therapies, announces today further progress in two investigator-initiated Phase II trials of setanaxib in diabetic kidney disease (DKD) and idiopathic pulmonary fibrosis (IPF).

The principal investigators leading the DKD trial decided, with agreement from Genkyotex, to expand the investigational network by adding centers in Germany, Denmark and New Zealand. New Zealand will be the first country to add centers and will be followed by Germany and Denmark. In addition, following the positive efficacy and safety results of the Company's Phase 2 trial of setanaxib in primary biliary cholangitis (PBC), the DKD trial protocol was amended to increase the dose to 400 mg BID. Importantly, 13 patients have already completed the full 48-week treatment and no safety signals have been identified. In DKD, the progressive loss of renal function is driven by fibrotic remodeling in renal glomeruli (glomerulosclerosis) and interstitium (interstitial fibrosis), and setanaxib has shown marked anti-inflammatory and anti-fibrotic effects in multiple preclinical models.

Separately, the U.S. Food and Drug Administration (FDA) and the relevant Institutional Review Boards (IRB) have now approved the protocol of the Phase II IPF trial, paving the way for patient enrollment, which is expected in the coming weeks. This trial is fully funded by an \$8.9 million grant awarded by the U.S. National Institutes of Health (NIH). The study is being led by Professor Victor Thannickal at the University of Alabama at Birmingham and includes a consortium of five centers of excellence. The study will evaluate the safety and efficacy of setanaxib in 60 IPF patients receiving standard of care therapy (pirfenidone or nintedanib).

Randomized patients will receive setanaxib at 400mg BID, the dose shown to achieve superior efficacy compared to 400mg OD, as well as favorable safety, in the recently completed 24-week Phase 2 trial in PBC. Setanaxib achieved regression of pulmonary fibrosis in a stringent preclinical model where instillation of bleomycin in aged mice results in persistent fibrosis and senescent myofibroblasts resistant to apoptosis. Setanaxib was able to reverse lung fibrosis by deactivating and clearing myofibroblasts through restored sensitivity to pro-apoptotic signals.

Philippe Wiesel, CMO of Genkyotex, said: *“We are very pleased to report positive developments in both the DKD and IPF clinical trials. We are pleased that the DKD trial has been expanded into three additional countries. This positive initiative will accelerate the evaluation of setanaxib in DKD. We are also excited to report that, following FDA approval, the IPF trial has now also received IRB clearance. Our recent results in PBC provided important dose response and safety information, which is being utilized to optimize these Phase II trials. We thank our academic collaborators for their continued commitment to the evaluation setanaxib in these diseases with high unmet needs.”*

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. Its unique platform enables the identification of orally available small-molecules which selectively inhibit specific NOX enzymes that amplify multiple disease processes such as fibrosis, inflammation, pain processing, cancer development, and neurodegeneration. Genkyotex is developing a pipeline of first-in-class product candidates targeting one or multiple NOX enzymes. The lead product candidate, setanaxib (GKT831), a NOX1 and NOX4 inhibitor has shown evidence of anti-fibrotic activity in a Phase II clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease). Based on its positive results, a phase 3 trial in PBC is being planned. setanaxib is also being evaluated in an investigator-initiated Phase II clinical trial in Type 1 Diabetes and Kidney Disease (DKD). A grant from the United States National Institutes of Health (NIH) of \$8.9 million was awarded to Professor Victor Thannickal at the University of Alabama at Birmingham (UAB) to fund a multi-year research program evaluating the role of NOX enzymes in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in fibrosis of the lungs, the core component of the program will be to conduct a Phase 2 trial with the setanaxib in patients with IPF. This product candidate may also be active in other fibrotic indications.

Genkyotex also has a versatile platform well-suited to the development of various immunotherapies (Vaxiclase). A partnership covering the use of Vaxiclase as an antigen per se (GTL003) has been established with Serum Institute of India Private Ltd (Serum Institute), the world’s largest producer of vaccine doses, for the development by Serum Institute of cellular multivalent combination vaccines against a variety of infectious diseases.

For further information, please go to www.genkyotex.com.



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