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Genkyotex announces the enrollment of the 1st patient in the Phase 2 trial of setanaxib in idiopathic pulmonary fibrosis (IPF)

This investigator-initiated trial funded by the National Institutes of Health (NIH) aims to evaluate the safety and efficacy of setanaxib in 60 patients

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and leader in NOX therapies, today announced the enrollment of the first patient in the investigator-initiated Phase 2 clinical trial of setanaxib, the Company's lead product candidate, in idiopathic pulmonary fibrosis (IPF). This study is conducted in accordance with the protocol approved by the U.S. Food and Drug Administration (FDA) and relevant Institutional review board (IRB).

The study is being led by Professor Victor Thannickal of the University of Alabama at Birmingham and includes a consortium of five research centers of excellence in the United States. It is fully funded by an $8.9 million grant awarded to Professor Thannickal's teams by the U.S. National Institutes of Health (NIH). The aim of the study is to evaluate the safety and efficacy of setanaxib in 60 IPF patients receiving standard treatment (pirfenidone or nintedanib) over a period of 24 weeks. The dose of setanaxib utilized will be 800 mg/day (400 mg BID), which was shown to achieve superior efficacy and a similarly favorable safety profile compared to 400 mg OD during the Phase 2 trial of setanaxib in primary biliary cholangitis (PBC). Efficacy endpoints include changes in plasma o,o'-dityrosine, a biomarker based on the mechanism of action of setanaxib, as well as standard clinical outcomes that include the 6-minute walk test and forced vital capacity (FVC). Plasma levels of collagen fragments, which could indicate anti-fibrotic activity, and the safety and tolerability of setanaxib will also be evaluated.

Dr. Philippe Wiesel, Executive Vice President and Chief Medical Officer of Genkyotex, says: "*We are delighted with the initiation of this Phase 2 trial of setanaxib and would like to congratulate Professor Victor Thannickal and his team for their efforts that have resulted in the enrollment of a first patient despite the challenging COVID-19 ongoing pandemic context. The launch of this Phase 2 trial in IPF highlights the considerable therapeutic potential of setanaxib in multiple fibrotic disorders. IPF is a highly devastating pulmonary disease with no satisfactory therapeutic solution that would slow or reverse its spread while also being well tolerated by patients. Given the anti-fibrotic effects demonstrated by setanaxib in our Phase 2 trial in primary biliary cholangitis and in numerous preclinical models, we are impatient to evaluate its efficacy in this new indication. Should the outcome be conclusive, it would provide additional clinical evidence that NOX enzyme inhibition could become a new paradigm for treating multiple fibrotic diseases and that our product candidate could play a leading role in this field*".

Idiopathic pulmonary fibrosis (IPF) is a chronic lung disease that results in fibrosis (scarring) of the lungs. This scarring of lung tissue causes dyspnea (shortness of breath) that worsens over time. The 5-year

survival rate for idiopathic pulmonary fibrosis is between 20 and 40%[1], i.e. it has a worse mortality rate than many types of cancer.

Setanaxib achieved regression of pulmonary fibrosis in a preclinical model where injection of bleomycin in adult 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.

Setanaxib showed it had a positive effect on liver stiffness in the Phase 2 study in primary biliary cholangitis (PBC) and the Company is in advanced talks with the regulatory authorities in the United States and Europe regarding a common registration strategy in this indication. Setanaxib is also being evaluated in an investigator-initiated Phase 2 clinical trial in another fibrotic disease, Type 1 Diabetes and Kidney Disease.

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 Phase II results, a phase 3 trial with setanaxib 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 this program is a Phase 2 trial with setanaxib in patients suffering from IPF for which the first patient has been enrolled in September 2020. 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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[1] Kim DS, Collard HR, King TE (2006). "Classification and natural history of the idiopathic interstitial pneumonias" *Proc Am Thorac Soc*. 3 (4): 285–292. DOI:10.1513/pats.200601-005TK PMID 1673819. PMC2658683.

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