Archamps (France), January 18, 2021 at 8.00 am CET

Genkyotex announces positive Phase 1 results demonstrating a favorable safety and pharmacokinetic profile of high-dose setanaxib

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and leader in NOX therapies, today announced positive Phase 1 data demonstrating a favorable safety and pharmacokinetic profile of high-dose setanaxib in healthy subjects.

The study showed that setanaxib was well tolerated at doses up to 1,600 mg/day, and displayed generally dose-proportional exposure. No safety signal and no dose limiting toxicity were identified across the doses tested, in a total of 46 healthy adult male and female subjects.

These results support the evaluation of substantially high doses, up to 1,600 mg/day, and provide an opportunity to pursue a pivotal clinical trial in patients with primary biliary cholangitis (PBC).

Previously, doses up to 800 mg/day were evaluated in a 24-week Phase 2 trial in PBC patients. In that trial, setanaxib dosed at 800 mg/day achieved reductions in markers of cholestasis including alkaline phosphatase, and in multiple non-invasive markers of liver fibrogenesis including liver stiffness and PRO-C3 and C3M. Significant improvement in fatigue was also achieved. At the same time, all doses tested were safe and very well tolerated with no safety signal compared to placebo.

"The results of this new phase 1 study confirm the excellent safety profile of setanaxib over a broad dose range. Moreover, the dose dependent effect observed in the previous Phase 2 study, together with the increased exposure achieved in this study, and give us the potential to launch a pivotal trial in PBC", **said Elias Papatheodorou, CEO of Genkyotex.**

As a reminder, following a friendly takeover bid initiated by Calliditas Therapeutics AB (publ) on Genkyotex, the results of which were announced on December 17, 2020, Calliditas Therapeutics AB now holds 86.24% of the share capital and theoretical voting rights of Genkyotex.

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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Disclaimer

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