Archamps (France), May 13, 2020 at 6.00 pm CEST

Genkyotex receives approval from the French Medicines Agency (ANSM) to initiate a Phase 1 clinical study with high-dose setanaxib

- ***This Phase 1 study will evaluate setanaxib at doses up to 1600 mg/day in up to 54 subjects***
- ***The study will support higher doses for future setanaxib trials including in IPF and PBC***
- ***Genkyotex is currently discussing the registration strategy for setanaxib in PBC with FDA and EMA***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today announced the approval from the French Medicines Agency (ANSM) to initiate a Phase 1 clinical study to investigate setanaxib at doses up to 1600 mg/day. Study initiation is anticipated in Q2 2020 with full results expected by the end of Q3 2020.

The evaluation of doses up to 1600 mg/day will support higher doses for future setanaxib trials, including in idiopathic pulmonary fibrosis (IPF) and primary biliary cholangitis (PBC). Genkyotex is currently discussing the registration strategy for setanaxib in PBC with the US Food and Drug Administration (FDA) and European Medicines Agency (EMA). The end of Phase 2 (EOP2) meeting with the FDA was not delayed due to COVID-19 situation and took place, at the end of April 2020, as planned.

This new Phase 1 study will investigate the safety, pharmacokinetics of setanaxib, as well as its potential for drug-drug interactions, at doses up to 1600 mg/day in up to 54 healthy adult male and female subjects. Taking into account the impact of the current COVID-19 pandemics, Genkyotex anticipates the initiation of the study in Q2 2020 with full results of both Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) by the end of Q3 2020.

The ANSM approval highlights setanaxib's favorable toxicology and clinical safety profile. To date, over 275 human subjects have been exposed to setanaxib in five Phase 1 and three Phase 2 clinical studies, and no safety signal and no dose limiting toxicity have been observed. The recent successful Phase 2 trial with setanaxib in PBC showed that the compound was safe and well-tolerated at all doses tested, including 400 and 800 mg/day. This Phase 2 trial demonstrated dose-dependent effects on markers of liver inflammation and fibrosis, and on quality of life measures including fatigue.

Furthermore, Genkyotex has also successfully completed a Phase 1 clinical study in healthy subjects to support the transition from the previous capsule formulation to the new high dose 400 mg tablet formulation.

"Regulatory approval to evaluate setanaxib at doses up to 1600 mg/day attests to the excellent safety profile of our lead compound. Successful results of this Phase 1 study will allow us to include higher doses in future setanaxib trials and reach the full efficacy potential of setanaxib. In addition, we are progressing with our regulatory agency discussions and will communicate the final outcome in the near future", **said Philippe Wiesel, M.D., Executive Vice President and Chief Medical Officer of Genkyotex.**

Next financial press release:

Q2 2020 business update and cash position: July 23, 2020 (after market)

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 2 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 with IPF scheduled to recruit patients in the course of 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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