Archamps (France), June 30, 2020 at 5.45 pm CEST

Genkyotex announces the dosing of the first subjects in its Phase 1 study with high-dose setanaxib

- ***The study aims to support the use of high-dose setanaxib in future clinical trials, including the pivotal registration trial of setanaxib in primary biliary cholangitis (PBC)***
- ***This Phase 1 study will evaluate setanaxib administered at doses up to 1,600 mg/day***
- ***Genkyotex anticipates superior efficacy in PBC with a higher dose***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today announced the initiation of a Phase 1 clinical study with high-dose setanaxib in healthy subjects.

This new Phase 1 study aims to support the inclusion of doses of up to 1,600 mg/day in future clinical trials, including the pivotal trial which will support the registration of setanaxib in primary biliary cholangitis (PBC). The study was approved by the French Medicines Agency (ANSM) in May 2020.

To date, five Phase 1 and three Phase 2 clinical studies have been conducted with setanaxib and no safety signal and no dose limiting toxicity have been observed. In the successfully completed PBC Phase 2 trial, 800 mg/day achieved consistently greater efficacy than 400 mg/day across multiple endpoints including improvements in markers of liver fibrosis, including a rapid reduction in liver stiffness and markers of collagen turnover. Superior efficacy was also achieved for fatigue, the main symptom reported by PBC patients, as well as for the cholestatic markers alkaline phosphatase (ALP) and gamma glutamyl transpeptidase (GGT).

Genkyotex recently provided additional clinical data from the PBC Phase 2 trial highlighting setanaxib's anti-fibrotic mechanism. Specifically, setanaxib improved markers of collagen turnover indicating reduced collagen synthesis and enhanced collagen degradation in patients with advanced liver fibrosis. These results provide further mechanistic insights for setanaxib's anti-fibrotic activity and provide an explanation for the rapid reduction in liver stiffness already reported in these high-risk patients. Considering setanaxib's excellent clinical safety profile, the company has decided to explore higher doses and anticipates superior efficacy based on the dose dependent effects observed in the Phase 2 PBC trial.

The single ascending dose (SAD) part of the Phase 1 study will provide pharmacokinetics information for doses up to 1,600 mg. Subsequently, the multiple ascending dose (MAD) part of the study will evaluate setanaxib doses of 1,200 and 1,600 mg/day over a 10-day dosing period. A total of up to 54 male and female healthy subjects will be included in the study.

Upon successful completion of this new Phase 1 study, Genkyotex plans to include higher doses in upcoming studies.

"We are excited to initiate this study in a timely fashion despite the COVID-19 pandemics. This study is an important component of our development plans for setanaxib in multiple fibrotic indications. In particular,

assessing these higher doses can support our registration strategy for setanaxib in PBC. We plan to provide further information about our pivotal program soon", **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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