Archamps (France), October 22, 2020 at 6.30 pm CEST

Genkyotex provides business update and reports cash position at September 30, 2020

- ***Cash and cash equivalents of €3.6 million as of September 30, 2020***
- ***Setanaxib granted ODD by the US FDA in PBC in October***
- ***1st patient enrolled in the Phase 2 trial in IPF in September***
- ***Phase 1 study with high-dose setanaxib on track with results expected by the end of Q4 2020***
- ***Discussions with the US and European health authorities on the registration strategy for setanaxib in PBC are ongoing***
- ***Ongoing transaction with Calliditas Therapeutics***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today reported cash and cash equivalents of €3.6 million as of September 30, 2020. The existing cash and cash equivalents provide cash runway to the end of February 2021.

Business update and outlook

The Company announced on August 13, 2020 an agreement for Calliditas Therapeutics AB to acquire a 62.7% controlling interest in Genkyotex SA from Genkyotex's largest shareholders and management team. The off-market block trade is expected to take place in the coming weeks and remains subject to customary conditions precedent, including clearance from the French Ministry of Economy and Finance regarding foreign investments in French companies. Calliditas is seeking to acquire all outstanding Genkyotex shares and, as soon as reasonably practicable after and subject to completion of the off-market block trade, will file with the French Financial Market Authority (Autorité des Marchés Financiers or "AMF") a mandatory simplified cash tender offer for the remaining Genkyotex shares on the same terms as the block trade (€2.80 per share in cash and contingent rights to additional cash payments subject to confirmation of regulatory approvals or marketing authorization of setanaxib no later than within ten years of the closing of the tender offer).

Clinical highlights

- **Registration strategy for setanaxib in primary biliary cholangitis (PBC):** in October 2020, setanaxib was granted orphan drug designation (ODD) by the US Food and Drug Administration (FDA). The company is currently discussing its registration strategy for setanaxib in PBC with the FDA and the EMA. Genkyotex will provide an outline of its late stage development plan once final approval of a common registration strategy has been obtained from these regulatory agencies.

- **Phase 2 trial of setanaxib in idiopathic pulmonary fibrosis:** the company announced on September 14, 2020 the enrollment of the 1st patient in a Phase 2 trial of setanaxib in IPF. This investigator-initiated 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 dosed at 800 mg/day (400 mg BID) in 60 IPF patients receiving standard treatment (pirfenidone or nintedanib) over a period of 24 weeks.

- **Phase 2 trial of setanaxib in diabetic kidney disease (DKD):** following the positive efficacy and safety results of the Company's Phase 2 trial of setanaxib in PBC, the DKD trial protocol was amended to increase the dose to 400 mg BID. To date, 29 patients have already completed the full 48-week treatment and no safety signals have been identified. The DKD trial is being conducted primarily in Australia, with work ongoing to activate centers in New Zealand, Denmark, and Germany. In the context of the COVID-19 pandemic, investigators have taken steps to minimize patient visits to investigation centers, in accordance with applicable rules and recommendations. Adequate drug supplies have been made available to the participating centers and patients. Despite the relatively low rate of SARS-Cov-2 infection in Australia, investigators cannot exclude a possible slowdown in new patient enrollment in the study.

- **Phase 1 study with setanaxib at high doses:** the Company has initiated an additional Phase 1 study to investigate the pharmacokinetics, safety profile, and potential for drug interactions of setanaxib at doses up to 1,600 mg. The study is on track and results are expected by the end of Q4 2020.

Financial highlights

On September 30, 2020, Genkyotex's cash and cash equivalents totaled €3.6 million vs. €5.1 million on June 30, 2020. The Company still expects its current resources to support anticipated operations until the end of February 2021, on a standalone basis and taking into account the facts and assumptions detailed in note 2.1 "Going concern" of the December 31, 2019 consolidated financial statements. The Company will continue to inform the market of the possible impacts of COVID-19 on its operations.

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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