Archamps (France), January 27, 2021 at 10 am CET

Genkyotex provides Q4 business update and reports cash position

- ***Positive data from Phase 1 clinical trial of high-dose setanaxib***
- ***Cash and cash equivalents of €1.2 million as of December 31, 2020***
- ***Calliditas Therapeutics AB (publ) tender offer closed in December 2020, resulting in an ownership percentage of 86.24%***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today reported cash and cash equivalents of €1.2 million as of December 31, 2020. The existing cash and cash equivalents provide cash runway to the end of February 2021. After this date Genkyotex will be required to fund the ongoing operations with new capital. Calliditas Therapeutics, the majority shareholder of Genkyotex, has expressed its intent to participate in such future financings on a pro rata basis. Until such financing has occurred, Calliditas will support Genkyotex by way of debt financing to enable the Company to meet its liabilities as they fall due and to carry on its normal business without any significant curtailment of operations.

Business update

On August 13, 2020, the Company announced the agreement by Calliditas to acquire 7,236,515 ordinary shares of Genkyotex, representing 62.7% of the share capital and voting rights from the Company's largest shareholders and management team.

On December 17, 2020, the Company announced the results of the tender offer, according to the results published on December 16, 2020 by the Autorité des marchés financiers (AMF), a total of 2,885,161 shares were tendered to the public offering. Following the close of the public offer, Calliditas held 10,121,676 shares of the Company representing 86.24% of the share capital and voting rights of the Company.

Clinical highlights

- **Phase 1 trial with setanaxib at higher doses:** in January 2021, the Company reported positive data from its Phase 1 clinical trial to evaluate the safety and pharmacokinetics of setanaxib at dosages up to 1,600 mg/day.

- **Development strategy for setanaxib in primary biliary cholangitis (PBC):** based on the Phase 1 trial data and interactions with US and European regulators in 2020, the Company recently announced that it plans to launch a pivotal and potentially registrational Phase 2/3 trial of setanaxib in patients with primary biliary cholangitis (PBC) in the second half of 2021. The final design and protocol details are subject to feedback from the US Food and Drug Administration (FDA).

- **Phase 2 proof-of-concept study in patients with head and neck cancer:** the Company recently announced that it plans to initiate a Phase 2 proof-of-concept study in patients with head and neck cancer before the end of the year. The trial will evaluate administration of setanaxib, targeting cancer associated fibroblasts (CAFs), in conjunction with immunotherapy.

- **Orphan drug designation (ODD) for setanaxib in primary biliary cholangitis (PBC):** setanaxib was granted orphan drug designation for the treatment of primary biliary cholangitis (PBC) by the US Food and Drug Administration (FDA) in October and by the European Commission in December, following the positive opinion from the Committee for Orphan Medicinal Products (COMP) of the European Medicines Agency (EMA).

- **Phase 2 trial of setanaxib in idiopathic pulmonary fibrosis (IPF):** the Company announced on September 14, 2020, the enrollment of the 1st patient in a Phase 2 trial of setanaxib in IPF. This study is conducted in accordance with a protocol approved by the U.S. Food and Drug Administration (FDA) and the relevant Institutional review board (IRB). 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 team 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 Company's Phase 2 trial with setanaxib in PBC, the DKD trial protocol was amended to increase the dose to 400 mg BID. To date, 29 patients have 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, but investigators cannot exclude a possible slowdown in new patient enrollment in the study.

Q4 2020 Financial highlights

On December 31, 2020, the Company's cash and cash equivalents totaled €1.2 million vs. €3.6 million on September 30, 2020. The Company's cash burn over the FY 2020 was primarily driven by R&D expenses related to the preparation of the End-Of-Phase 2 meeting with the FDA and the Phase 1 study to investigate higher dose with setanaxib.

The Company expects its current resources to support anticipated operations until the end of February 2021, taking into account the facts and assumptions detailed in note 2.1 "Going concern" of the December 31, 2019 consolidated financial statements and the condensed consolidated interim financial statements prepared in accordance with IFRS for the six-month period ended June 30, 2020. Genkyotex will be required to fund the ongoing operations with new capital. Calliditas Therapeutics, the majority shareholder of Genkyotex, has expressed its intent to participate in such future financings on a pro rata basis. Until such financing has occurred, Calliditas will support Genkyotex by way of debt financing.

Financial results to September 30, 2020

As part of the accounting consolidation process of Calliditas, the Company prepared consolidated financial statements for the nine-month period ended September 30, 2020 under IFRS, as issued by the International Accounting Standards Board.

These financial statements are available in the Investors section of the Company's website. The Company does not plan going-forward to report on standalone nine-month financial information or on quarterly financial information (other than in relation to its quarterly cash and cash equivalents position).

In thousands of euros	Nine-month period ended September 30, 2020	At December 31, 2019
Other Income	35	142
Research & Development expenses	(9,627)	(6,305)
Subsidies and Research Tax Credit	356	899
General & Administrative expenses	(1,757)	(2,160)
Operating loss	**(10,993)**	**(7,425)**
Net loss	**(11,017)**	**(7,203)**
Net loss per share (in euros)	(0.99)	(0.88)

Given its stage of development, the Company has not generated any sales to date, as all of its product candidates are in the Research & Development (R&D) phase.

The consolidated net loss as at September 30, 2020 is €11,017 thousand against €7,203 thousand as at December 31, 2019. This increase is mainly driven by the impairment of the SIIL contract as a consequence of the impact of Covid-19 on the development timelines (negative impact of €5.8 M), partially offset by the reduction of R&D costs due to the end of the Phase 2 clinical trial with setanaxib in primary biliary cholangitis (PBC) and reduced G&A costs.

Governance

Following the closing of the off-market block trade on November 3, 2020, the members of the board of directors other than Elias Papatheodorou, Chief Executive Officer, resigned. Elmar Schnee, Chairman of the board of Calliditas, Renée Aguiar-Lucander, Chief Executive Officer of Calliditas and Jonathan Schur, Group General Counsel of Calliditas, have been appointed as members of the Board of directors. Elmar Schnee has been elected President of the Board of directors. Dr. Philippe Wiesel, Executive Vice President and Chief Medical Officer of Genkyotex, has left the Company to pursue new professional projects. He will remain as a consultant to Calliditas.

COVID-19 update

In the context of the COVID-19 pandemic, the Company continues to closely monitor the evolution of the official guidelines and recommendations in order to protect its employees and contractors. The Company has also implemented strategies to mitigate the impact of the global shutdown on its business and operations.

To date, except for the impairment of the SIIL contract (see above), the COVID-19 pandemic has had a limited impact on the Company's operations. Genkyotex will continue to monitor the impact of the COVID-19 pandemics on the conducting of clinical trials and discussions with health authorities and, depending on the evolution of the pandemics and of its potentially material impact on such trials and discussions, will keep the market informed.

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. Its leading 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). Clinical trials in PBC and head and neck cancer with setanaxib are being planned in 2021 and investigator led studies in Type 1 Diabetes and Kidney Disease (DKD) and in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in fibrosis of the lungs, are ongoing.

For further information, please go to *www.genkyotex.com*

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CONTACTS

GENKYOTEX
Alexandre Grassin
CFO
Tel.: +33 (0)5 61 28 70 60
investors@genkyotex.com

NewCap
Dušan Orešanský
Tel.: +33 1 44 71 94 92
genkyotex@newcap.eu

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