Archamps (France), February 18, 2021 at 7.15 pm CET

GENKYOTEX ANNOUNCES 2020 ANNUAL FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

- ***Cash runway until early March 2021***
- ***Beyond early March 2021 a capital infusion is required in which Calliditas has agreed to support Genkyotex***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announces its consolidated financial results for the year ended December 31, 2020[1], in accordance with International Financial Reporting Standards (IFRS), as adopted by the European Union. A summary of the consolidated financial statements is included below.

On December 31, 2020, Genkyotex had cash and cash equivalents of €1.6 million. The Company expects that its current cash position is sufficient to fund planned operations to early March 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. Until such financing has occurred, Calliditas has expressed its willingness to support Genkyotex by way of a bridge 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.

- Given its stage of development, Genkyotex has not generated any sales to date, as all of its product candidates are in the Research & Development (R&D) phase. The subsidies and Research Tax Credit (€469 thousand) mainly correspond to the expected French Research Tax Credit for 2020.

- R&D expenses are 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 €5.8m), partially offset by the reduction of R&D costs due to the end of the Phase 2 clinical trial of setanaxib in primary biliary cholangitis (PBC)

- G&A expenses increase by 0.7 M€ mainly due to fees incurred as part of the transaction with Calliditas AB.

- Genkyotex recorded a consolidated net loss of -14.1 million for the year ended December 31, 2020 compared to a net loss of -€7.2 million at December 31, 2019.

[1] Consolidated accounts were approved by the Board on February 17, 2021. The auditors have completed their procedures on the consolidated financial statements. They will continue with the post-balance sheet event review until issuance of their audit report.

Selected 2020 unaudited financial results

€ thousands - IFRS	At December 31, 2020	At December 31, 2019
Income from customers agreement	-	-
Research & Development expenses	(11,607)	(6,305)
Subsidies and Research Tax Credit	469	899
General & Administrative expenses	(2,885)	(2,160)
Other Income	38	142
Current operating loss	**(14,055)**	**(7,425)**
Other operating expenses	-	-
Operating loss	**(14,055)**	**(7,425)**
Net loss for the period	**(14,060)**	**(7,203)**
Net loss per share (in euros)	(1.25)	(0.88)

The consolidated statement of financial position and the consolidated income statement prepared in accordance with IFRS, as adopted by the European Union, for the year ended December 31, 2020 are included in appendix 1 of this press release.

2020 key highlights and outlook for 2021

- **Tender offer of Calliditas:** 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. This block trade was finalized on November 3, 2020.

  On December 17, 2020, the Company announced the results of the tender offer launched by Calliditas on all of its outstanding shares. 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 theoretical voting rights of the Company.

- **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.

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 COVID19 pandemics on the conducting of clinical trials and discussions with health authorities and, depending on the evolution of the pandemic 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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Disclaimer

This press release may contain forward-looking statements by the company with respect to its objectives. Such statements are based upon the current beliefs, estimates and expectations of Genkyotex's management and are subject to risks and uncertainties such as the company's ability to implement its chosen strategy, customer market trends, changes in technologies and in the company's competitive environment, changes in regulations, clinical or industrial risks and all risks linked to the company's growth. These factors as well as other risks and uncertainties may prevent the company from achieving the objectives outlined in the press release and actual results may differ from those set forth in the forward-looking statements, due to various factors. Without being exhaustive, such factors include uncertainties involved in the development of Genkyotex's products, which may not succeed, or in the delivery of Genkyotex's products marketing authorizations by the relevant regulatory authorities and, in general, any factor that could affects Genkyotex's capacity to commercialize the products it develops. No guarantee is given on forward-looking statements which are subject to a number of risks, notably those described in the universal registration document filed with the AMF on April 30, 2020 under number D.20-0434, and those linked to changes in economic conditions, the financial markets, or the markets on which Genkyotex is present. Genkyotex products are currently used for clinical trials only and are not otherwise available for distribution or sale.

Appendix 1 – Statement of consolidated financial position and consolidated income statement as of December 31, 2020

The statement of consolidated financial position and consolidated income statement of Genkyotex S.A. were prepared in accordance International Financial Reporting Standards (IFRS), as adopted by the European Union. The auditors have completed their procedures on the consolidated financial statements. They will continue with the post-balance sheet event review until issuance of their audit report. The consolidated financial statements for the period ended December 31, 2020 were approved by Board of Directors on February 17, 2021 and will be submitted to the shareholders at the Shareholders' Meeting planned in June 2021.

GENKYOTEX **Consolidated Income Statement** **(in thousands of EUR)**	**12/31/2020** **12 months**	**12/31/2019** **12 months**
Sales	-	-
Cost of sales	-	-
Gross margin	**-**	**-**
Research and development expenses		
Research and development expenses	(11,677)	(6,305)
Subsidies	469	899
General and administrative expenses	(2,885)	(2,160)
Other income	38	142
Current operating loss	**(14,055)**	**(7,425)**
Other operating income	-	-
Other operating expenses	-	-
Operating loss	**(14,055)**	**(7,425)**
Financial income	(79)	(190)
Financial expenses	75	412
Pre-tax loss	**(14,060)**	**(7,203)**
Income tax (expense)	-	-
Net loss for the period	**(14,060)**	**(7,203)**
Attributable to owners of the parent company	(14,060)	(7.203)
Non-controlling interests	-	-
Weighted average number of shares in circulation	11'284'380	8'146'178
Basic loss per share (EUR/share) (1)	**(1.25)**	**(0.88)**
Diluted loss per share (EUR/share) (1)	**(1.25)**	**(0.88)**

GENKYOTEX Consolidated Statement of Financial Position (in thousands of EUR)	12/31/2020	12/31/2019
ASSETS		
Intangible assets	2,755	9,086
Property, plant and equipment	181	154
Non-current financial assets	28	29
Total non-current assets	**2,964**	9,270
Other current assets	1,559	1,500
Current financial assets	-	-
Cash and cash equivalents	1,613	2,417
Total current assets	**3,172**	3,917
Total Assets	**6,136**	13,186
LIABILITIES AND EQUITY		
Equity		
Capital	11,736	8,683
Additional paid-in capital	4,991	126,118
Cumulative translation adjustments	(2,732)	(2,732)
Accumulated other comprehensive loss	(524)	(697)
Accumulated deficit attributable to owners of the parent	(3,266)	(114,332)
Net loss attributable to owners of the parent	(14,060)	(7,203)
Equity attributable to owners of the parent	**2,657**	9,836
Non-controlling interests	-	-
Total equity	**2,657**	9,836
Non-current liabilities		
Employee benefit obligations	827	1.348
Non-current financial liabilities	53	17
Other non-current liabilities	141	-
Non-current liabilities	**1,021**	1,364
Current liabilities		
Current financial liabilities	122	848
Financial derivative	-	64
Trade payables	1,683	562
Other current liabilities	654	512
Current liabilities	**2,458**	1,986
Total Liabilities and Equity	**6,136**	13,186