Archamps (France), February 27, 2020 at 6.00 pm CET

GENKYOTEX ANNOUNCES 2019 ANNUAL FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

- ***Current cash reach to end of February 2021***
- ***Company has no outstanding financial debt as all outstanding convertible bonds were converted in early 2020***
- ***Phase 2 study with setanaxib in IPF expected to start in the coming weeks***

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, 2019[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.

Elias Papatheodorou, CEO of Genkyotex, says: "*2019 was a pivotal year that saw our company reach several milestones in the advanced clinical development of setanaxib. From a clinical perspective, the results of our phase 2 study with setanaxib in primary biliary cholangitis demonstrated the ability of our compound to significantly reduce liver stiffness and improve patients' quality of life, while being well tolerated. These important findings make us confident about setanaxib potential in multiple fibrotic diseases. We are looking forward to our end-of-Phase 2 meeting with the FDA in which we would like to obtain an agreement on the design of the Phase 3 study. Simultaneously, setanaxib is evaluated in two other Phase 2 studies, one in diabetic kidney disease associated with type 1 diabetes (DKD) currently underway, and the other in idiopathic pulmonary fibrosis (IPF) that should start in the coming weeks. Both studies are funded by grants provided to our academic partners. In this context, the amount of €4.9 million raised in February 2020 with the support of our long-standing shareholders extends our financial visibility until the end of February 2021 and allows us to focus on the development of setanaxib in our targeted fibrotic indications and explore its potential in other therapeutic areas with high unmet needs.*"

On December 31, 2019, Genkyotex had cash and cash equivalents of €2.4 million which does not include the €4.9 million raised in February 2020. The Company expects that its current cash position is sufficient to fund planned operations to the end of February 2021.

- 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 received correspond to the expected French research tax credit for 2019 (€899 thousand).

[1] Consolidated accounts were approved by the Board on February 24, 2020. 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.

- R&D expenses are mainly related to the costs of the Phase 2 clinical trial of setanaxib in primary biliary cholangitis (PBC). The study was completed in May 2019, driving the annual costs down compared to 2018. As previously communicated, the Phase 2 clinical trial in Diabetic Kidney Disease, initiated by investigators, is being financed by the Juvenile Diabetes Research Foundation (JDRF Australia) and the Baker Institute.

- Genkyotex recorded a consolidated net loss of -€7.2 million for the year ended December 31, 2019 compared to a net loss of -€11.4 million at December 31, 2018.

Selected 2019 financial results

€ thousands - IFRS	At December 31, 2019	At December 31, 2018
Income from customers agreement	-	750[(b)]
Research & Development expenses[(a)]	(6,305)	(9,282)
Subsidies and Research Tax Credit	899	893
General & Administrative expenses	(2,160)	(2,836)
Other Income	142	44
Current operating loss	**(7,425)**	**(10,430)**
Other operating expenses	-	-
Operating loss	**(7,425)**	**(10,430)**
Net loss for the period	**(7,203)**	**(11,417)**
Net loss per share (in euros)[(a)]	(0.88)	(1.46)

(a) The net loss per share as at December 31, 2018 has been adjusted to reflect the effect of the 10-for-1 reverse stock split of Genkyotex's common shares which became effective March 29, 2019.

(b) In 2018, the Company received €750 thousand corresponding to the upfront payment resulting from the execution of the Serum of India Institute Private Ltd (SIIPL) licensing agreement extension announced on June 25, 2018. In accordance with the terms of this agreement, which provides for milestone payments based on development and sales, no payments have been received in 2019.

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, 2019 are included in appendix 1 of this press release.

2019 key highlights and outlook for 2020

- **Positive effect on liver stiffness in the PBC phase 2 trial with setanaxib**: In May 2019, the Company reported top-line results of its PBC phase 2 trial with setanaxib. In this trial, setanaxib achieved clinically meaningful reductions in liver stiffness, and statistically significant reductions in gamma glutamyl transpeptidase (GGT) ($p<0.002$) and alkaline phosphatase (ALP) ($p<0.001$) over the 24-week treatment period, but did not achieve statistical significance in the reduction of GGT at week 24, the predefined primary efficacy endpoint. A post-hoc analysis reported in July 2019 showed that statistical significance of $p=0.02$ was achieved for the primary endpoint for 400mg BID at week 24 when correcting for the non-normal distribution in the 400mg OD group. Moreover, Setanaxib 400mg BID achieved a substantial reduction (-22%) in liver stiffness in patients with advanced disease (≥9.6 kPa at baseline). In these patients, setanaxib also achieved clinically meaningful reductions in GGT (-32%) and ALP (-24%) at week 24. Importantly, setanaxib 400mg BID also achieved a statistically significant improvement in quality of life, and was well tolerated at all doses. Collectively, these data indicate that setanaxib could become a new therapeutic option for the difficult to treat patient populations with advanced liver fibrosis in PBC

and other liver diseases, including advanced NASH. Based on these positive results, a phase 3 trial in PBC is being planned.

The Company will be discussing with regulators to finalize the design of its phase 3 trial with setanaxib in primary biliary cholangitis (PBC) and plans to enroll patients with inadequate response to UDCA standard of care therapies, including the emerging population of patients receiving generically available PPAR agonists (e.g. bezafibrate). This is in contrast with other phase 3 programs which exclude these patients. The Company expects its phase 3 to include measurements of liver stiffness and quality of life, which remains an unaddressed medical need. An end-of-Phase 2 meeting with the FDA is scheduled and an agreement on the phase 3 design with the US Food and Drug Administration (FDA) is envisioned in the first half of 2020.

- **IPF phase 2 trial with setanaxib to be initiated in the following weeks:** The FDA and the relevant Institutional Review Board (IRB) have approved the protocol of the Phase 2 IPF trial, allowing the initiation of patient enrollment. The first site initiation is anticipated shortly, with patient enrollment expected to start in the coming weeks. The trial size, design, and endpoints have been defined to adequately support the initiation of a phase 3 program in case of positive phase 2 outcomes. This trial is funded by an $8.9 million grant awarded by the U.S. National Institutes of Health (NIH). The study is being led by Professor Victor Thannickal at the University of Alabama at Birmingham and includes a consortium of five investigational centers of excellence in the United-States. The study will evaluate the safety and efficacy of setanaxib in 60 IPF patients receiving standard of care therapy (pirfenidone or nintedanib). Enrolled patients will be treated with setanaxib or matching placebo for 24 weeks. Efficacy endpoints include changes in plasma o,o'- dityrosine, a biomarker based on the mechanism of action of setanaxib, as well as standard clinical outcomes which include the 6-minute walk distance and forced vital capacity (FVC). The safety and tolerability of setanaxib will be also evaluated.

- **Extension of the Phase 2 DKD trial with setanaxib in New Zealand, Denmark and Germany:** The principal investigators leading the diabetic kidney disease (DKD) trial decided, with agreement from Genkyotex, to expand the investigational network by adding centers in Germany, Denmark and New Zealand. Ethical committees have approved the study protocol in New Zealand and three sites are pending activation. Germany and Denmark will follow.
  Considering 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. As of today, 13 patients have already completed the full 48-week treatment and no safety concerns have been reported.

- **WHO recognized NOX enzymes as new therapeutic class:** The Company announced in July 2019 that the World Health Organization (WHO) recognized NOX inhibitors as a new therapeutic class, while approving the new stem "naxib". The WHO recommended setanaxib as the international non-proprietary name (INN, or generic name) for GKT831.

- **New oncology grant:** The Company announced in February 2019 that its academic partner, Professor Gareth Thomas of the University of Southampton (UK), was awarded a Biotherapeutics Drug Discovery Project grant by Cancer Research UK (CRUK), a leading cancer research and awareness organization based in the UK, to conduct a research program focused on the role of NOX inhibition in oncology. The £260 thousand grant will support the research program entitled "Combination immunotherapy for breast cancer: targeting cancer-associated fibroblasts to improving therapeutic vaccination." This is the second grant provided by CRUK to Professor Thomas for the evaluation of NOX inhibitors in oncology.

Next financial press release:

Q1 2020 business update and cash position: April 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 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 with IPF scheduled to recruit patients in first semester 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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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 January 16, 2020 under number 20-0012, 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, 2019

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, 2019 were approved by Board of Directors on February 24, 2020 and will be submitted to the shareholders at the Shareholders' Meeting planned on June 10, 2020.

GENKYOTEX **Consolidated Income Statement** **(in thousands of EUR)**	**12/31/2019** **12 months**	**12/31/2018** **12 months**
Sales	-	-
Cost of sales	-	-
Gross margin	**-**	**-**
Income from customers agreement	-	750
Research and development expenses		
Research and development expenses	(6.305)	(9.282)
Subsidies	899	893
General and administrative expenses	(2.160)	(2.836)
Other income	142	44
Current operating loss	**(7.425)**	**(10.430)**
Other operating income	-	-
Other operating expenses	-	-
Operating loss	**(7.425)**	**(10.430)**
Financial income	(190)	(1.185)
Financial expenses	412	197
Pre-tax loss	**(7.203)**	**(11.417)**
Income tax (expense)	-	-
Net loss for the period	**(7.203)**	**(11.417)**
Attributable to owners of the parent company	*(7.203)*	*(11.417)*
Non-controlling interests	-	-
	12/31/2019	**12/31/2018**
Basic loss per share (EUR/share) (1)	**(0,88)**	**(1,46)**
Diluted loss per share (EUR/share) (1)	**(0,88)**	**(1,46)**

(1) The loss per share in 2018 has been adjusted to reflect the effect of the 10-for-1 reverse stock split of Genkyotex's common shares, as approved by Genkyotex' shareholders at the Extraordinary General Meeting on January 24, 2019 and implemented by the Board of Directors the same day.

GENKYOTEX Consolidated Statement of Financial Position (in thousands of EUR)	12/31/2019	12/31/2018
ASSETS		
Intangible assets	9.086	10.221
Property, plant and equipment	154	51
Non-current financial assets	29	64
Total non-current assets	**9.270**	**10.336**
Other current assets	1.500	1.932
Current financial assets	-	3.280
Cash and cash equivalents	2.417	11.345
Total current assets	**3.917**	**16.557**
Total Assets	**13.186**	**26.893**
LIABILITIES AND EQUITY		
Equity		
Capital	8.683	7.785
Additional paid-in capital	126.118	162.015
Cumulative translation adjustments	(2.732)	(2.258)
Accumulated other comprehensive loss	(697)	(316)
Accumulated deficit attributable to owners of the parent	(114.332)	(117.917)
Net loss attributable to owners of the parent	(7.203)	(25.773)
Equity attributable to owners of the parent	**9.836**	**23.535**
Non-controlling interests	-	-
Total equity	**9.836**	**23.535**
Non-current liabilities		
Employee benefit obligations	1.348	822
Non-current financial liabilities	17	115
Non-current liabilities	**1.364**	**937**
Current liabilities		
Current financial liabilities	848	288
Financial derivative	64	
Trade payables	562	1.312
Other current liabilities	512	820
Current liabilities	**1.986**	**2.421**
Total Liabilities and Equity	**13.186**	**26.893**