

GENKYOTEX ANNOUNCES 2018 ANNUAL FINANCIAL RESULTS AND PROVIDES CORPORATE UPDATE

- ***Company's cash runway expected to extend through first quarter of 2020***
- ***About 90% of patients have completed full 24-week treatment period in Phase 2 clinical trial of GKT831 in PBC and no dropouts or treatment interruptions due to pruritus have been reported to date***
- ***Interim efficacy results abstract selected for an oral presentation during general session of International Liver Conference (ILC 2019)***
- ***Last patient out from the PBC Phase 2 clinical trial is expected by mid-March 2019 and final results expected in spring 2019 according to plan***

Genkyotex (Euronext Paris & Brussels: FR0011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announces its consolidated financial results for the year ended December 31, 2018¹, in accordance with International Financial Reporting Standards (IFRS). A summary of the consolidated financial statements is included below.

Elias Papatheodorou, CEO of Genkyotex, says: *"In 2018, we achieved significant progress in advancing the development of GKT831 in multiple indications. Most importantly, the compelling interim data from our Phase 2 trial in PBC is indicative of GKT831's potential to treat a wide-range of fibrotic indications and represents the first clinical proof-of-concept for the novel therapeutic class of NOX inhibitors. We look forward to final results and especially data related to fibrosis and quality of life."*

On December 31, 2018, Genkyotex had cash and cash equivalents of €10.3 million, versus €12.8 million on September 30, 2018. The Company expects that its current cash position, after taking into account the full conversion of the convertible notes with warrants attached issued in August 2018 (of which 175 notes out of 500 notes have been converted to date), is sufficient to fund planned operations through first quarter of 2020.

- 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. In 2018, the Company received €750 thousand corresponding to the upfront payment resulting from the execution of the Serum of India Institute Private Ltd (SIPL) extension agreement announced on June 25, 2018. The subsidies mainly correspond to the expected French research tax credit for 2018 (€893 thousand) accrued for 2018.

¹ Consolidated accounts were approved by the Board on February 28th, 2019. These accounts have been audited and the certification report will be issued after verification of the management report

- R&D expenses related to the costs of the ongoing Phase 2 clinical trial of GKT831 in primary biliary cholangitis (PBC) drove the current operating loss of -€10.4 million at December 31, 2018. As previously communicated, the Phase 2 clinical trial in Diabetic Kidney Disease, initiated by investigators, is being entirely financed by the Juvenile Diabetes Research Foundation (JDRF Australia) and the Baker Institute, and thus had no impact on the Company's recurring operating loss.
- Genkyotex recorded a consolidated net loss of -€11.4 million (-€0.15 per share without the effect of the 10-for-1 reverse stock split of Genkyotex's common shares currently in progress) for the year ended December 31, 2018 compared to a net loss of -€25.8 million at December 31, 2017 (precision being made that without the one-time items related to the reverse takeover and the non-cash share-based payment for a total of €15.2 million, the adjusted consolidated net loss would have been -€10.5 million in 2017).

Selected 2018 Financial Results

€ thousands - IFRS	At December 31, 2018	At December 31, 2017
Income from customers agreement	750	-
Research & Development expenses (a)	(9,282)	(9,475)
Subsidies and Research Tax Credit	893	669
General & Administrative expenses (a)	(2,836)	(5,299)
Other Income	44	-
Current operating loss (a)	(10,430)	(14,104)
Other operating expenses (b)	-	(11,408)
Operating loss	(10,430)	(25,512)
Net loss for the period (c)	(11,417)	(25,773)
Net loss per share (in euros) (d)	(0.15)	(0.39)

(a) In 2017, the current operating loss includes a non-cash share-based payment expense of €1,990 thousand in Research & Development expenses and €1,838 thousand in General & Administrative expenses

(b) In 2017, the other operating expenses include the quotation cost of €10,898 thousand (non-cash item) and restructuring costs for €510 thousand

(c) In 2017, the net loss excluding onetime items related to the reverse takeover and the non-cash share-based payment expense would be -€10,537 thousand

(d) Net loss per share is presented before the effect of the 10-for-1 reverse stock split of Genkyotex's common shares currently in progress.

The consolidated statement of financial position and the consolidated income statement prepared in accordance with IFRS for the year ended December 31, 2018 are included in appendix 1 of this press release.

2018 Key Highlights

- Announced positive interim results of the ongoing Phase 2 clinical trial of GKT831, the Company's lead product candidate, in PBC, where both primary and secondary efficacy endpoints were met with high statistical significance. After just 6 weeks of treatment, GKT831 achieved time and dose dependent improvements in markers of cholestasis, liver injury and inflammation.
- Announced 3 positive safety monitoring board (SMB) recommendations confirming the clinical favorable safety profile of GKT831 observed during the study.
- Expanded the license agreement with the SIPL for the Vaxicase platform to the developed world, bringing the overall agreement to approximately €150 million in development and commercial milestones.

- Announced that academic partner, Professor Victor Thannickal at the University of Alabama at Birmingham (UAB), was awarded an \$8.9 million grant by the United States National Institutes of Health (NIH) to evaluate GKT831 in patients with idiopathic pulmonary fibrosis (IPF).

Business Update and Outlook for 2019

- **Phase 2 trial of GKT831 in patients with PBC is on track:** this 24-week phase 2 trial is being conducted across a global network of investigational sites in Europe, North America and Israel, on 111 randomized patients. Last patient is expected to complete the 24-week treatment period by mid-march 2019 and the final results are expected in spring 2019. Importantly, to date, about 90% of patients have completed the 24-week treatment period and no dropouts or treatment interruptions due to pruritus have been reported. In addition to markers of cholestasis and liver inflammation, the final analysis will evaluate potential benefits on liver fibrosis, quality of life (i.e. itching and fatigue), bile acid metabolism, and autoimmune processes.
- **Abstract presenting the interim efficacy results of the phase 2 trial in PBC** was selected for an oral presentation during general session of International Liver Conference (ILC 2019) to be held in Vienna (Austria) from April 10 to 14, 2019. Further information regarding the presentation will be provided prior to the conference.
- **Ongoing investigator-initiated Phase 2 trial of GKT831 in patients with Type 1 diabetes and diabetic kidney disease (DKD):** this 48-week Phase 2 clinical trial is currently recruiting and no SAEs or discontinuations have been reported to date. This investigator-initiated trial is being entirely financed by the Juvenile Diabetes Research Foundation (JDRF) Australia and the Baker Institute. A target of 142 patients expected to be enrolled in up to 15 centers in Australia.
- **Investigator-initiated Phase 2 trial of GKT831 in lung fibrosis (IPF) expected to be initiated in the first half of 2019:** the core component of this program, financed by a \$8.9 million grant from US NIH to Professor Thannickal at UAB, will be to conduct a 24-week investigator-initiated Phase 2 trial of GKT831. This will be a randomized, double-blind, placebo-controlled Phase 2 clinical trial of GKT831 in 60 patients with IPF receiving standard of care therapies.
- **Advancing research on NOX inhibitors in oncology:** on February 2019, the Company announced that 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, 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 2019 business update and cash position: April 25, 2019 (after market)

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. A leader in NOX therapies, its unique therapeutic approach is based on a selective inhibition of NOX enzymes that amplify multiple disease processes such as fibrosis, inflammation, pain processing, cancer development, and neurodegeneration.

Genkyotex's platform enables the identification of orally available small-molecules that selectively inhibit specific NOX enzymes. Genkyotex is developing a pipeline of first-in-class product candidates targeting one or multiple NOX enzymes. The lead product candidate, GKT831, a NOX1 and NOX4 inhibitor is evaluated in a phase 2 clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease) and 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 the program will be to conduct a Phase 2 trial with the GKT831 in patients with IPF. This product candidate may also be active in other fibrotic indications. Its second product candidate, GKT771, is a NOX1 inhibitor targeting multiple pathways in angiogenesis, pain processing, and inflammation, currently undergoing preclinical testing.

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. This partnership could generate approximately €150 million in future revenues for Genkyotex, before royalties on sales.

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



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 affect 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 registration document (document de référence) registered by the French Markets Authority (the AMF) on 27 April 2018 under number R.18-037, 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.

INVESTORS	MEDIA	US
NewCap Dušan Orešanský, Tristan Roquet Montégon and Emmanuel Huynh +33 1 44 71 94 92 genkyotex@newcap.eu	NewCap Nicolas Merigeau, Arthur Rouillé +33 1 44 71 00 15 genkyotex@newcap.eu	LifeSci Advisors, LLC Brian Ritchie +1-212-915-2578 britchie@lifesciadvisors.com

Appendix 1 – Statement of consolidated financial position and consolidated income statement as of December 31, 2018

The statement of consolidated financial position and consolidated income statement of the Company were prepared in accordance International Financial Reporting Standards (IFRS). The audit procedures on the consolidated financial statements have been performed. The consolidated financial statements for the period ended December 31, 2018 were approved by Board of Directors on February 28, 2019 and will be submitted to the shareholders at the Shareholders' Meeting on June 13, 2019.

GENKYOTEX	12/31/2018	12/31/2017
Consolidated Statement of Financial Position		
(in thousands of EUR)		
ASSETS		
Intangible assets	9 653	10 221
Property, plant and equipment	31	51
Non-current financial assets	45	64
Total non-current assets	9 729	10 336
Other current assets	2 157	1 932
Current financial assets	-	3 280
Cash and cash equivalents	10 309	11 345
Total current assets	12 466	16 557
Total Assets	22 195	26 893
LIABILITIES AND EQUITY		
Equity		
Capital	7 935	7 785
Additional paid-in capital	124 183	162 015
Cumulative translation adjustments	(2 361)	(2 258)
Accumulated other comprehensive loss	(514)	(316)
Accumulated deficit attributable to owners of the parent	(103 383)	(117 917)
Net loss attributable to owners of the parent	(11 417)	(25 773)
Equity attributable to owners of the parent	14 442	23 535
Non-controlling interests	-	-
Total equity	14 442	23 535
Non-current liabilities		
Employee benefit obligations	996	822
Non-current financial liabilities	-	115
Non-current liabilities	996	937
Current liabilities		
Current financial liabilities	3 641	288
Trade payables	2 214	1 312
Other current liabilities	903	820
Current liabilities	6 757	2 421
Total Liabilities and Equity	22 195	26 893

GENKYOTEX Consolidated Income Statement (in thousands of EUR)	12/31/2018 12 months	12/31/2017 12 months
Sales	-	-
Cost of sales	-	-
Gross margin	-	-
Income from customers agreement	750	-
Research and development expenses		
Research and development expenses	(9 282)	(9 475)
Subsidies	893	669
General and administrative expenses	(2 836)	(5 299)
Other income	44	-
Current operating loss	(10 430)	(14 104)
Other operating income	-	-
Other operating expenses	-	(11 408)
Operating loss	(10 430)	(25 512)
Financial expenses	(1 185)	(309)
Financial income	197	54
Pre-tax loss	(11 417)	(25 768)
Income tax (expense)	-	(5)
Net loss for the period	(11 417)	(25 773)
<i>Attributable to owners of the parent company</i>	<i>(11 417)</i>	<i>(25 773)</i>
<i>Non-controlling interests</i>	<i>-</i>	<i>-</i>
	12/31/2018	12/31/2017
Basic loss per share (EUR/share)	(0,15)	(0,39)
Diluted loss per share (EUR/share)	(0,15)	(0,39)
Basic loss per share (EUR/share) - proforma (1)	(1,46)	(3,90)
Diluted loss per share (EUR/share) - proforma (1)	(1,46)	(3,90)

(1) The loss per share - proforma reflects 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.