Archamps (France), September 26, 2018, 5:45 pm CEST

Genkyotex Announces First-Half 2018 Financial Results

- ***Cash and cash equivalents of €9.3 million at June 30, 2018, excluding capital raised in August and upfront SIIL payment***
- ***Interim results of Phase 2 trial of GKT831 in patients with PBC expected in early November 2018***

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announces its consolidated financial results for the six months ended June 30, 2018, prepared in accordance with IFRS. First half financial statements for 2018 were subject to a limited review by the Company's statutory auditors, and the interim financial report is available in the Investors section of the Company's website (in French).

First-half 2018 financial highlights

In thousands of euros	At June 30, 2018	At June 30, 2017[1]
Other revenues	750	
Research & Development expenses	(4,518)	(5,665)
Subsidies and Research Tax Credit	429	395
General & Administrative expenses	(1,471)	(3,640)
Recurring operating loss	**(4,811)**	**(8,910)**
Other operating expenses	-	(11,408)
Operating loss	**(4,811)**	**(20,318)**
Net loss	**(4,776)**	**(20,368)**
Net loss per share (in euros)	(0.06)	(0.38)

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. On June 30, 2018, the other revenues correspond to the upfront payment resulting from the execution of the SIIPL extension agreement announced on June 25, 2018.

The operating loss at June 30, 2018 of €4,811 thousand was mainly driven by the R&D expenses primarily related to the costs of the ongoing Phase 2 clinical trial of GKT831 in primary biliary cholangitis (PBC).

The operating loss of €20,318 thousand at June 30, 2017, included non-recurring items (with no impact on the cash position of the Company) and restructuring costs for a total of €15'325 thousand and related to the strategic combination carried out by Genkyotex in February 2017. Excluding these one-time items, the operating loss of the Company at June 30, 2017, would have been €4'993 thousand.

[1] The first half of 2017 includes Genkyotex's results of operations as well as Genticel's results of operations from February 28, 2017

Genkyotex's cash and cash equivalents amounted to €9.3 million on June 30, 2018, as compared to €14.6 million on December 31, 2017, in-line with the Company's expectations. Genkyotex expects this cash position to support currently planned operations until the end of Q3 2019.
Genkyotex's cash burn for the six months ended June 30, 2018, was primarily driven by expenses related to the ongoing Phase 2 trial of GKT831 in PBC. Subsequent to June 30, 2018, the Company received the upfront payment resulting from the execution of the SIIPL extension agreement, the reimbursement of the French Research tax credit for 2017 of €0.6 million and €4.9 million received as part of the up to €7.5 million in nominal value financing obtained from Yorkville Advisors Global LP through the issuance of convertible notes with warrants attached, announced on August 20, 2018. As of today, 50 convertible notes (OCA) have been converted into shares.

Business update and outlook

During the first half of 2018, the Company's key development-related activities focused on:

- **Evaluating the efficacy of GKT831 in PBC, a fibrotic liver disorder**. Earlier today, the Company announced the completion of patient enrollment for its Phase 2 trial of GKT831 in patients with Primary Biliary Cholangitis (PBC). The company's network of investigational centers across 9 countries delivered outstanding performance resulting in the enrollment of 111 patients, exceeding the original target of 102 patients. This Phase 2 trial is a 24-week, double-blind, placebo-controlled study, evaluating the safety and efficacy of GKT831 in patients with PBC and inadequate response to ursodeoxycholic acid (UDCA). Randomized patients were allocated to three treatment arms: UDCA plus placebo, UDCA plus GKT831 at 400mg once a day, and UDCA plus GKT831 at 400mg twice a day. Genkyotex expects interim results in early November 2018 and final results in Spring 2019.
- **Evaluating the efficacy of GKT831 in diabetic kidney disease (DKD), a progressive fibrotic disorder.** Investigators initiated in 2017 a 48-week Phase 2 clinical trial with GKT831 in patients with type 1 diabetes and nephropathy.
- **Evaluating the efficacy of GKT831 in idiopathic pulmonary fibrosis (IPF), a fibrotic lung disorder.** On July 31, 2018, Genkyotex announced that the US National Institutes of Health awarded an $8.9 million grant to Professor Victor Thannickal of the University of Alabama at Birmingham (UAB) to fund a multi-year research program evaluating the role of NOX enzymes in IPF, a chronic lung disease that results in fibrosis of the lungs. The core component of the program will be to conduct a 24-week Phase 2 trial of the Company's lead product candidate, GKT831, in patients with IPF.
- **Expanding the Company's NOX platform by continuing exploratory preclinical research programs.** The Company continues to explore the therapeutic value of NOX inhibition in central nervous system disorders and oncology, and to seek opportunities for non-dilutive grant financing to support the preclinical evaluation of drug candidates in these therapeutic areas. Most recently, data in a preclinical model also showed that GKT831 efficiently targeted cancer associated fibroblasts in prostate cancer and abrogated the pro-tumorigenic influence of the tumor micro-environment. The results of this study, which was conducted by Dr. Natalie Sampson and colleagues at the Medical University of Innsbruck, were published in the *International Journal of Cancer* (https://doi.org/10.1002/ijc.31316).
- **Continuing to execute on the partnership with the Serum Institute for Vaxiclase.** On June 25, 2018, the Company announced that it had extended the license agreement for its Vaxiclase platform with the Serum Institute of India Private Ltd (SIIPL), the world's largest vaccine manufacturer, to include the developed world in their addressable markets. The initial agreement, signed in 2015, covered emerging pharmaceutical markets. Following the expansion of the agreement to these major markets, Genkyotex became eligible to receive an additional

€100 million, bringing the overall agreement to approximately €150 million[2] in upfront payment, development and commercial milestones before royalties. Vaxiclase is a technology platform ideally suited for immunotherapies against multiple infectious diseases or cancers, and SIIPL is utilizing it to develop a pertussis vaccine.

Genkyotex will host a conference call in English today, September 26, 2018 at 06:15 pm CEST / 12:15 pm EDST, followed by a Q&A session.

The call is accessible via the below teleconferencing information:

France: +33 1 72 72 74 03
Switzerland: +41 445 831 805
US: +1 646 722 49 16
UK: +44 207 194 37 59
Belgium: +32 240 358 16

Pin: 85798253#

Following the conclusion of the live call, a replay will be available for 90 days. To access the replay, please dial the following number:

Tel: +33 1 70 71 01 60
Access code: 418789188#

Next financial press release:

Q3 2018 business update and cash position: October 24, 2018 (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 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 (U.S. NIH) of $8.9 million has been 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 has been established with Serum Institute of India Private Ltd (Serum Institute) and could generate approximately €150 million in future revenues for Genkyotex, before royalties on sales.

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

[2] The overall amount of this agreement is provided in euros for information purposes and is based on the €/$ currency rate as at the signature date of the restated agreement.

Disclaimer

This press release and the information it contains does not constitute an offer or solicitation to buy, sell or hold Genkyotex shares in any country, in particular any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration, exemption from registration or other qualification under the securities laws of any such jurisdiction.

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 registration document (document de reference) 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.

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