Archamps (France), September 19, 2019 at 06:00 pm CEST

Genkyotex Announces First Half 2019 Results

- ***Final setanaxib phase 2 results in PBC showed statistical significance for primary endpoint when corrected for non-normal variability***
- ***Data to be presented at an upcoming international scientific conference***
- ***WHO recognized NOX inhibitors as a new therapeutic class***

Genkyotex (Euronext Paris & Brussels: FR00013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today announces its consolidated financial results for the six months ended June 30, 2019, prepared in accordance with IFRS. 2019 half-year condensed consolidated financial statements were subject to a limited review by the Company's statutory auditors. A summary of 2019 half-year condensed consolidated financial statements is included in this press release, and the 2019 half-year financial report is available in the Investors section of Genkyotex's website (in French). Genkyotex's cash and cash equivalents amounted to €4.5 million on June 30, 2019.

First half 2019 financial highlights

In thousands of euros	At June 30, 2019	At June 30, 2018
Other revenues	0	750
Research & Development expenses	(3,830)	(4,518)
Subsidies and Research Tax Credit	627	429
General & Administrative expenses	(1,546)	(1,471)
Recurring operating loss	**(4,750)**	**(4,811)**
Other operating expenses		-
Operating loss	**(4,750)**	**(4,811)**
Net loss	**(4,625)**	**(4,776)**
Net loss per share (in euros)	(0.58)	(0.06)

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 net loss of €4,625 thousand was mainly driven by the R&D expenses primarily related to the costs of the Phase 2 clinical trial of setanaxib in primary biliary cholangitis (PBC).

Genkyotex's cash and cash equivalents amounted to €4.5 million on June 30, 2019, as compared to €10.2 million on December 31, 2018. Genkyotex expects that this cash position will support currently planned operations until the end of Q1 2020. These financial statements were prepared on a going concern basis taking into account the facts and assumptions detailed in the note 2.1 “going concern” of the 2019 half-year condensed consolidated financial statements.

Genkyotex’s cash burn for the six months ended June 30, 2019, was primarily driven by expenses related to the Phase 2 trial of setanaxib in PBC. Subsequent to June 30, 2019, the Company agreed with Yorkville Advisors Global, a U.S.-based investment manager, on a 12-month extension of the conversion period for its remaining €1.6 million convertible notes held by Yorkville. This has been achieved by Genkyotex buying-back from Yorkville on August 19, 2019 its remaining €1.6 million convertible notes due August 20, 2019, and simultaneously issuing to Yorkville new convertible notes equivalent to the remaining existing convertible notes and due August 20, 2020. The Company is expecting to receive the French Research tax credit for 2018 of €0.9 million in the coming months.

Business update and outlook

The Company announced in July 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.

During the first half of 2019, Genkyotex’s key development-related activities focused on:

- **Evaluating the efficacy of setanaxib in PBC, a fibrotic liver disorder**. The Company reported in May 2019 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.

- **Evaluating the efficacy of setanaxib in diabetic kidney disease (DKD), a progressive fibrotic disorder.** Investigators previously initiated a 48-week Phase 2 clinical trial with setanaxib in patients with type 1 diabetes and nephropathy. Patient recruitment is ongoing and no safety signals have been reported to date.

- **Evaluating the efficacy of setanaxib in idiopathic pulmonary fibrosis (IPF), a fibrotic lung disorder.** In 2018, the US National Institutes of Health awarded an $8.9 million grant to Professor Victor Thannickal of the University of Alabama at Birmingham 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 is to conduct a 24-week Phase 2 trial with setanaxib in patients with IPF.

  In July 2019, the US Food and Drug Administration approved an Investigational New Drug (IND) application allowing the initiation of a Phase 2 trial of setanaxib in patients with IPF. Patient enrollment is expected to begin in the coming months.

- **Expanding the Company's NOX platform by continuing exploratory preclinical research programs.** Genkyotex continues to explore the therapeutic value of NOX inhibition in other indications, including oncology, and to seek opportunities for non-dilutive grant financing to support the preclinical evaluation of drug candidates in these therapeutic areas.

  The Company announced in February 2019 that Professor Gareth Thomas of the University of Southampton, United Kingdom (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. This is the second grant provided by CRUK to Professor Thomas for the evaluation of NOX inhibitors in oncology.

Next financial press release:

Q3 2019 business update and cash position: October 24, 2019 (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 results, a phase 3 trial 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 the program will be to conduct a Phase 2 trial with the setanaxib in patients with IPF. 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 or investors@genkyotex.com*

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