

Genkyotex announces first-half 2020 results and business update

- **Cash and cash equivalents of €5.1 million at June 30, 2020**
- **First patient enrolled in Phase 2 trial of setanaxib in IPF**

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTIX), a biopharmaceutical company and leader in NOX therapies, today provides business update and announces its consolidated financial results for the six months ended June 30, 2020, prepared in accordance with IFRS.

Business update and outlook

The Company announced on August 13, 2020 an agreement for Calliditas Therapeutics AB to acquire a controlling interest in Genkyotex SA. Calliditas has agreed to acquire from Genkyotex's largest shareholders and management team, through an off-market block trade, ordinary shares of Genkyotex representing 62.7% of the share capital and voting rights of Genkyotex. The off-market block trade is expected to take place in October 2020 and remains subject to customary conditions precedent, including clearance from the French Ministry of Economy and Finance regarding foreign investments in French companies. Calliditas is seeking to acquire all outstanding Genkyotex shares and, as soon as reasonably practicable after and subject to completion of the off-market block trade, Calliditas will file with the French Financial Market Authority (*Autorité des Marchés Financiers* – the “AMF”) a mandatory simplified cash tender offer for the remaining Genkyotex shares on the same terms as the block trade (€2.80 per share in cash and contingent rights to additional cash payments subject to confirmation of regulatory approvals or marketing authorization of setanaxib no later than within ten years of the closing of the tender offer).

During the first half of 2020, Genkyotex’s clinical activity focused mainly on the following key elements:

- **Registration strategy for setanaxib in primary biliary cholangitis (PBC):** Genkyotex is currently discussing the registration strategy for setanaxib in PBC with the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). The End Of Phase 2 (EOP2) meeting with the FDA was not delayed by the COVID-19 situation and took place at the end of April 2020, as planned. Genkyotex requested and obtained, at the end of June 2020, scientific advice from the EMA’s Scientific Advice Working Party (SAWP) that provides a path for the late stage development and registration of setanaxib in PBC. Initial feedback was also received from the FDA following the End Of Phase 2 meeting held in April. Genkyotex will communicate on its late stage development plan once final approval of a common registration strategy has been obtained from the FDA and the EMA.
- **Phase 2 trial of setanaxib in idiopathic pulmonary fibrosis:** 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 the protocol approved by the U.S. Food and Drug Administration (FDA) and relevant Institutional review board (IRB). The 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 teams by the U.S. National Institutes of Health (NIH). The aim of the study is to evaluate the safety and efficacy of setanaxib in 60 IPF patients receiving standard treatment (pirfenidone or nintedanib) over a period of 24 weeks. The dose of setanaxib utilized will be 800 mg/day (400 mg BID), which was shown to achieve superior efficacy and a similarly favorable safety profile compared to 400 mg OD during the Phase 2 trial of setanaxib in primary biliary cholangitis (PBC). 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 that include the 6-minute walk test and forced vital capacity (FVC). Plasma levels of collagen fragments, which could indicate anti-fibrotic activity, and the safety and tolerability of setanaxib will also be evaluated.

- **Phase 2 trial of setanaxib in diabetic kidney disease (DKD):** following 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. To date, 28 patients have already 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. Adequate drug supplies have been made available to the participating centers and patients. Despite the relatively low rate of SARS-Cov-2 infection in Australia, investigators cannot exclude a possible slowdown in new patient enrollment in the study.
- **Phase 1 study with setanaxib at high doses:** the Company has initiated an additional Phase 1 study to investigate the pharmacokinetics, safety profile, and potential for drug interactions of setanaxib at doses up to 1,600 mg. The study results are expected by the end of Q4 2020.

First-half 2020 financial highlights

The 2020 half-year financial report is available in the Investors section of Genkyotex's website (in French - <https://www.genkyotex.com/fr/>). Genkyotex's cash and cash equivalents amounted to €5.1 million at June 30, 2020.

In thousands of euros	At June 30, 2020	At June 30, 2019
Other revenues	37	-
Research & Development expenses	(2,285)	(3,830)
Subsidies and Research Tax Credit	268	627
General & Administrative expenses	(868)	(1,546)
Recurring operating loss	(2,850)	(4,750)
Other operating expenses	-	-
Operating loss	(2,850)	(4,750)
Net loss	(2,675)	(4,625)
Net loss per share (in euros)	(0.24)	(0.58)

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 net loss is €2,675 thousand vs €4,625 thousand a year before. This improvement is mainly driven by the reduction of R&D costs due to the end of the Phase 2 clinical trial of setanaxib in primary biliary cholangitis (PBC) and reduced G&A costs.

Genkyotex's cash and cash equivalents amounted to €5.1 million at June 30, 2020, compared to €2.4 million at December 31, 2019. Genkyotex expects that this cash position will support currently planned operations until the end of February 2021. Half-year 2020 consolidated financial statements were subject to a limited review by the Company's statutory auditors. 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 2020 half-year condensed consolidated financial statements presented in accordance with IFRS. The auditor's review report includes an emphasis of matter paragraph for the material uncertainty related to going concern.

Genkyotex's cash burn over the first half of 2020 was primarily driven by R&D expenses related to the preparation of the End Of Phase 2 meeting with the FDA and the Phase 1 to investigate higher dose with setanaxib.

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, the COVID-19 pandemic had a limited impact on the Company's operations. Genkyotex will continue to monitor the impact of the COVID-19 pandemics on the conducting of clinical trials and discussions with health authorities and, depending on the evolution of the pandemics and of its potentially material impact on such trials and discussions, will keep the market informed.

Next financial press release:

Q3 2020 business update and cash position: October 22, 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 suffering from IPF for which the first patient has been enrolled in September 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

GKTX
LISTED
EURONEXT



CONTACTS

GENKYOTEX

Alexandre Grassin

CFO

Tel.: +33 (0)5 61 28 70 60

investors@genkyotex.com

NewCap

Dušan Orešanský

Tel.: +33 1 44 71 94 92

genkyotex@newcap.eu

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 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.