

Archamps (France), May 13, 2021 at 7.00 pm CEST

Genkyotex provides business update and reports cash position at March 31, 2021

- **Cash and cash equivalents of €3.8 million as of March 31, 2021**
- **Rights issue of €5 million in March 2021 completed**
- **Positive data from Phase 1 clinical trial of high-dose setanaxib**

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today reported cash and cash equivalents of €3.8 million as of March 31, 2021. The existing cash and cash equivalents provide cash runway to end of July 2021.

Business update

On March 24, 2021, the Company announced that it had raised €5 million through a rights issue in France. Following this capital increase, the Company's main shareholder, Calliditas Therapeutics AB (publ), holds 90.2% of the share capital and voting rights of the Company.

Clinical highlights

- **Phase 1 study with setanaxib at high doses:** in January 2021, the Company reported positive interim data from its Phase 1 clinical trial to evaluate the safety and pharmacokinetics of setanaxib at dosages up to 1,600 mg/day in healthy subjects.
- **Development strategy for setanaxib in primary biliary cholangitis (PBC):** Genkyotex continues to plan the initiation of a pivotal Phase 2/3 study in primary biliary cholangitis (PBC), during the second half of 2021, with final design and protocol details subject to feedback from the US Food and Drug Administration (FDA). The launch of the study is subject to the availability of adequate financial resources.
- **Phase 2 proof-of-concept study in patients with head and neck cancer:** the Company announced, on January 22, 2021, that it plans to initiate before the end of this year a Phase 2 proof-of-concept study in patients with head and neck cancer. The launch of the study is subject to the availability of adequate financial resources. The trial will evaluate administration of setanaxib, targeting cancer associated fibroblasts (CAFs), in conjunction with immunotherapy.
- **The Company continues to support two investigator-initiated Phase 2 studies with setanaxib,** respectively, in Type 1 Diabetes and Kidney Disease (DKD) (study financed by the Juvenile Diabetes Research Foundation of Australia and the Baker Institute for which 34 patients have completed the full 48-week treatment with no safety signals identified) and in idiopathic pulmonary fibrosis (IPF) (study financed by the NIH led by Professor Victor Thannickal of the University of Alabama at Birmingham evaluating the safety and efficacy of setanaxib dosed at 800 mg/day (400 mg BID) over a period of 24 weeks).

Q1 2021 Financial highlights

On March 31, 2021, the Company's cash and cash equivalents totaled €3.8 million vs. €1.2 million on December 31, 2020, and included the net proceeds of €5.05m from the rights issue completed on March 24. The Company's cash burn in Q1 2021 was primarily driven by R&D expenses related to chemistry, manufacturing and control (CMC) activities and the Phase 1 trial to investigate higher dose with setanaxib.

The Company expects its current resources to support anticipated operations until the end of July 2021, taking into account the facts and assumptions detailed in note 2.1 "Going concern" of the December 31, 2020 consolidated financial statements. Calliditas has confirmed its intention, so long as the Company remains its controlled subsidiary, to continue supporting the Company, if need be, so as to enable the Company to meet its liabilities as they fall due and to carry on its normal business without any significant curtailment of operations. Calliditas has also advised the Company that the ability of Calliditas to provide funding for Genkyotex further developments could be adversely affected if there is a delay in launching Calliditas' planned squeeze-out offer (*offre de retrait*) and related delisting of the Company from the regulated markets of Euronext Paris and Euronext Brussels because, as long as Genkyotex remains a listed company, an effective integration of its research and development and clinical development activities with those of Calliditas is made more difficult and the financing of Genkyotex will require the completion of costly and time consuming rights offerings. Failure to obtain the necessary financing could lead the Company to interrupt or reduce its envisioned research and development and clinical development activities.

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 events & press releases:

Annual General Meeting: May 27, 2021

Q2 2021 financial update: August 19, 2021

Half Year Results 2021: September 30, 2021

Q3 2021 financial update: October 21, 2021

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. Its leading 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). Clinical trials in PBC and head and neck cancer with setanaxib are being planned in 2021 and investigator led studies are supported by the Company in Type 1 Diabetes and Kidney Disease (DKD) and in idiopathic pulmonary fibrosis (IPF), a chronic lung disease that results in fibrosis of the lungs, are ongoing.

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

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