Archamps (France), July 23, 2020 at 6.00 pm CEST

GENKYOTEX PROVIDES BUSINESS UPDATE AND REPORTS CASH POSITION AT JUNE 30, 2020

- *CASH AND CASH EQUIVALENTS OF €5.1 MILLION AS OF JUNE 30, 2020*
- *ONGOING DISCUSSIONS WITH US FDA AND EUROPEAN EMA ON THE REGISTRATION STRATEGY FOR SETANAXIB IN PBC*
- *PHASE 1 STUDY WITH HIGH-DOSE SETANAXIB LAUNCHED IN JUNE*
- *LAUNCH OF THE PHASE 2 IPF TRIAL STILL EXPECTED IN 2020 DESPITE THE COVID-19 SITUATION*

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today reported cash and cash equivalents of €5.1 million as of June 30, 2020. This amount includes the French research tax credit of €0.9 million which was received by the Company in April 2020. The existing cash and cash equivalents provide cash runway to the end of February 2021.

Clinical highlights

- **End-of-phase-2 discussions with regulators for setanaxib in 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.
- **IPF phase 2 trial:** the launch of the study, already approved by the FDA and the relevant Institutional Review Board (IRB), is still expected in 2020 despite the COVID-19 situation. This investigator-initiated trial is fully funded by an $8.9 million grant awarded by the U.S. National Institutes of Health (NIH). The study is being led by Professor Victor Thannickal at the University of Alabama at Birmingham and includes a consortium of five investigational centers of excellence in the United States. The study will evaluate the safety and efficacy of setanaxib in 60 IPF patients receiving standard of care therapy (pirfenidone or nintedanib) during a 24-week treatment. 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 and the safety and tolerability of setanaxib will also be evaluated. The trial size, design, and endpoints are adequate to support the initiation of a Phase 3 program should there be a positive outcome.

- **DKD phase 2 trial:** following the positive efficacy and safety results of the Company's Phase 2 trial of setanaxib in primary biliary cholangitis (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 investigator-initiated trial is being conducted primarily in Australia, with work ongoing to activate centers in New Zealand, Denmark and Germany.
- **Phase 1 study with setanaxib at high doses:** the Company received, in May 2020, approval from the French Medicines Agency (ANSM) to initiate a Phase 1 clinical study in up to 54 healthy subjects to investigate the pharmacokinetics, potential for drug interactions and safety profile of setanaxib at doses up to 1,600mg. The first subjects were dosed at the end of June and the enrollment process is ongoing.

Financial highlights

On June 30, 2020, Genkyotex's cash and cash equivalents totaled €5.1 million vs. €5.6 million on March 31, 2020. This amount includes the French research tax credit of €0.9 million which was received by the Company in April 2020. Despite the COVID-19 situation, the Company still expects its current resources to support anticipated operations until the end of February 2021, taking into account the facts and assumptions detailed in note 2.1 "Going concern" of the December 31, 2019 consolidated financial statements. The Company will continue to inform the market of the possible impacts of COVID-19 on its operations.

Next financial press release:

2020 half-year results: September 17, 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 with IPF scheduled to recruit patients in the course of 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*

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