Archamps (France), January 16, 2020 at 07:30 pm CET

GENKYOTEX PROVIDES BUSINESS UPDATE AND REPORTS GROSS CASH POSITION AT DECEMBER 31, 2019

- *GROSS CASH AND CASH EQUIVALENTS OF €2.4 MILLION AS OF DECEMBER 31, 2019*
- *PHASE 2 IPF NIH-FUNDED TRIAL FIRST PATIENT IN EXPECTED FEBRUARY 2020*
- *PHASE 3 PBC TRIAL DESIGN EXPECTED TO BE AGREED WITH FDA WITHIN THE FIRST HALF OF 2020*
- *NO CONVERTIBLE DEBT OUTSTANDING AS OF JANUARY 15, 2020*

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announced today gross cash and cash equivalents of €2.4 million as of December 31, 2019. The existing gross cash and cash equivalents provide cash runway to end of Q1 2020.

Clinical highlights

During the fourth quarter of 2019, Genkyotex reported progress in clinical development of setanaxib:

- The Company is in discussions with regulators to finalize the design of its phase 3 trial in primary biliary cholangitis (PBC) and plans to enroll patients with inadequate response to standard of care therapies, including the emerging population of patients receiving generically available PPAR agonists (e.g. bezafibrate). This is in contrast with other phase 3 programs which exclude these patients. The phase 3 will include measurements of liver stiffness and quality of life which remains an unaddressed medical need. An agreement on the phase 3 design with the US Food and Drug Administration (FDA) is expected in the first half of 2020.

- The FDA and the relevant Institutional Review Board (IRB) have approved the protocol of the Phase 2 IPF trial, allowing the initiation of patient enrollment. The first site initiation is anticipated shortly, with patient enrollment expected to start in February. The trial size, design, and endpoints are adequate to support the initiation of a phase 3 program in case of positive outcomes.

  This 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). Enrolled patients will be treated with setanaxib or matching placebo for 24 weeks. 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 which include the 6-minute walk distance and forced vital capacity (FVC). The safety and tolerability of setanaxib will be also evaluated.

- The principal investigators leading the diabetic kidney disease (DKD) trial decided, with agreement from Genkyotex, to expand the investigational network by adding centers in Germany, Denmark and New Zealand. Ethical committees have approved the study protocol in New Zealand and three sites are pending activation. Germany and Denmark will follow.

- 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. As of today, 13 patients have already completed the full 48-week treatment and no safety concerns have been reported.

Research highlights

Genkyotex continues to explore the therapeutic value of NOX inhibition in additional therapeutic areas, including oncology. The Company expects to secure non-dilutive grant financing to support its ongoing collaborations with academic partners.

Financial highlights

On December 30, 2019, Genkyotex's gross cash and cash equivalents totaled €2.4 million vs. €3.1 million on September 30, 2019. Genkyotex expects its current resources to support anticipated operations until March 31, 2020 taking into account the facts and assumptions detailed in the note 2.1 "going concern" of the 2019 half year condensed consolidated financial statements. The Company is actively looking into all options to obtain additional financing for its development.

In addition, the Company was informed on January 15, 2020 of the conversion into new shares of the last convertible bonds issued to the YA II PN, Ltd fund managed by Yorkville Advisors Global LP. The Company has therefore no longer any convertible debt as of this date.

Taking into account the conversion into new shares of all the outstanding convertible bonds mentioned immediately above, to the company's knowledge, the ownership of share capital and voting rights of the company is as follows:

Shareholders	Ownership of share capital and voting rights as of 15 January 2020			
	On a non diluted basis		On a diluted basis[1]	
	Number of shares	% of share capital and voting rights[2]	Number of shares	% of share capital and voting rights[2]
Andera Partners Funds[3] (formerly EDRIP)	1,863,079	20.47%	1,863,079	19.72%
Eclosion2 SA	1,393,285	15.31%	1,393,285	14.75%
Vesalius Biocapital II SA, SICAR	691,529	7.60%	691,529	7.32%
Neomed Innovation V L.P.	544,550	5.98%	544,550	5.76%
Management & Employees	434,730	4.78%	686,883	7.27%
Other investors	4,165,055	45.76%	4,258,806	45.08%
Treasury shares[4]	9,037	0.10%	9,037	0.10%
Total	9,101,265	100.00%	9,447,170	100.00%

(1) Taking into account (i) 972,512 warrants and 2,486,533 stock-options issued and granted by the Company as of 15 January 2020, exercisable or not, giving rise, respectively, to the subscription of 97,251 and 248,653 new shares of the Company.
(2) Theoretical voting rights. All the shares other than the treasury shares held by the Company have the same voting rights.
(3) Fonds Biodiscovery 2, Fonds Biodiscovery 3, Partenariat et Innovation 2 and Partenariat et Innovation 3, represented by Andera Partners.
(4) Shares held as of 15 January 2020 under the terms of a liquidity provider agreement entered into with Kepler on 23 April 2018.

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*

GKTX LISTED EURONEXT

ELIGIBLE PEA PME

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 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 26 April 2019 under number R.19-014, 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.

CONTACT

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