Archamps (France), October 24, 2019 at 06:00 pm CEST

GENKYOTEX PROVIDES BUSINESS UPDATE AND REPORTS CASH POSITION AT SEPTEMBER 30, 2019

- *CASH AND CASH EQUIVALENTS OF €3.1 MILLION AS OF SEPTEMBER 30, 2019*
- *FRENCH RESEARCH TAX CREDIT OF €0.9 MILLION FOR 2018 WAS RECEIVED IN OCTOBER*
-
- *COMPANY HAS REQUESTED FROM THE FDA AN END OF PHASE 2 MEETING*
- *GENKYOTEX TO PRESENT TWO ABSTRACTS AT THE UPCOMING AASLD 2019 LIVER MEETING AND WILL PARTICIPATE TO THE GILBERT DUPONT NASH MEETING IN PARIS ON OCTOBER 29TH*

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announced today cash and cash equivalents of €3.1 million as of September 30, 2019. The existing cash and cash equivalents, including the French research tax credit for 2018 of €0.9 million received subsequent to the close of the third quarter, provide cash runway to end of Q1 2020.

Clinical highlights

During the third quarter of 2019, Genkyotex announced the positive results from post-hoc analyses of its PBC phase 2 trial. In this large trial, setanaxib achieved statistical significance (p=0.02) for the primary endpoint with the 400mg twice a day (BID) versus placebo, after correction of non-normal distribution in the 400mg once a day group. Post-hoc analyses also indicated that advanced patients, defined as baseline liver stiffness $\geqslant$9.6 kPa, achieved particularly important reductions in liver stiffness and in markers of cholestatic injury. Specifically, setanaxib 400mg BID achieved marked reductions in gamma glutamyl transpeptidase (GGT) (-32%), alkaline phosphatase (ALP) (-24%), and liver stiffness (-22%) after just 6 months of treatment. Taken together with an excellent safety profile and meaningful improvements in quality of life, these results indicate that setanaxib could become an important novel therapy for PBC patients.

Company has requested an end of Phase 2 meeting from the US Food and Drug Administration (FDA) to obtain guidance from the agency about the Company's plans to proceed to Phase 3 with setanaxib in primary biliary cholangitis.

During the quarter, the Company also announced 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.
- the United States Food and Drug Administration (FDA) approved the Investigational New Drug (IND) application allowing the initiation of the Phase 2 trial with setanaxib in patients with idiopathic pulmonary fibrosis (IPF) in the coming months.

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. During the second quarter of 2019, the Company announced the publication of data in Clinics and Research in Hepatology and Gastroenterology showing that its anti-fibrotic drug candidate, GKT831, prevents multiple complications of portal hypertension in a preclinical model.

In addition, two abstracts were accepted for presentation during the upcoming 2019 AASLD Liver Meeting (Boston, November 8-12). Abstract 1283 entitled, "*The NOX1/4 inhibitor GKT831 reduces liver stiffness, attenuates cholestasis, and improves quality of life in patients with primary biliary cholangitis,*" will be presented by Dr Jonathan Huang (University of Rochester Medical Center, NY, United States) at the Hynes Convention Center, Hall B, November 9, 2pm. Abstract 2152 entitled, "*A novel, second generation NADPH oxidases 1 and 4 (NOX1/4) inhibitor attenuates TGF-induced myofibroblast activation in vitro and delays disease progression in a high fat diet-induced NASH model,*" will be presented by Dr Philippe Wiesel (Chief Medical Officer, Genkyotex) at the Hynes Convention Center, Hall B, November 11, 8am.

Financial highlights

On September 30, 2019, Genkyotex's cash and cash equivalents totaled €3.1 million vs. €4.5 million on June 30, 2019. This amount does not include the receipt of the French research tax credit for 2018 of €0.9 million that was received in October 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.

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.

Media relations
Sophie Baumont
LifeSci Advisors
+33 6 2774 74 49
sophie@lifesciadvisors.com

Investor relations
Brian Ritchie
LifeSci Advisors, LCC
+1 212 915 2578
britchie@lifesciadvisors.com