Archamps (France), April 25th, 2018 at 05:45 pm CEST

GENKYOTEX REPORTS MARCH 31, 2018 CASH POSITION AND PROVIDES BUSINESS UPDATE

- ***Cash and cash equivalents of €12.5 million as of March 31st, 2018, in line with expectations***
- ***Cash runway to Q3 2019***
- ***Company now expects interim results from phase 2 trial of GKT831 in Primary Biliary Cholangitis Fall 2018 and final results in H1 2019***

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today reported cash and cash equivalents of €12.5 million, on March 31st, 2018.

Elias Papatheodorou, CEO of Genkyotex, comments: "*We continue to achieve significant clinical development progress with our lead product candidate, GKT831, and enrollment of patients in our Primary Biliary Cholangitis (PBC) phase 2 trial is ongoing across nine countries. In our early-stage development program, we recently announced that academic collaborators independently confirmed in a preclinical model of prostate cancer that GKT831 efficiently targeted cancer associated fibroblasts. Looking ahead, we anticipate that interim results from our phase 2 PBC trial of GKT831 will be available in the Fall of 2018 and full results in the first half of 2019. Importantly, we now expect our cash runway to extend through the third quarter of 2019, allowing us to fund the phase 2 trial in PBC to completion.*"

Financial highlights:

On March 31st, 2018, Genkyotex's cash, cash equivalents and liquid investments amounted to €12.5 million vs. €14.6 million on December 31st, 2017, in line with the Company's expectations. Genkyotex's cash burn was primarily driven by investments in the ongoing phase 2 trial in PBC and ongoing preclinical development work with GKT771. Based on anticipated lower operating expenses, we expect the Company's cash runway to now extend to Q3 2019, through multiple significant clinical milestones for GKT831, including the final results of the phase 2 trial in PBC.

Clinical highlights:

Patient enrolment continues in Phase 2 trial of GKT831 in patients with PBC

- Patient enrollment in the Phase 2 clinical trial of GKT831, the Company's NOX1 and NOX4 inhibitor, in PBC continues across a global network of investigational centers in the United States, Canada, Belgium, Germany, Greece, Italy, Spain, the United Kingdom, and Israel. 53 centers have been initiated to date and are actively screening potential subjects. Planned center activation continues and the Company expects a total of 55 to 60 centers to be activated for this trial.

- This phase 2 trial is a 24-week, double-blind, placebo controlled, evaluating the safety and efficacy of GKT831 in patients with PBC and inadequate response to ursodeoxycholic acid (UDCA). A total of 102 PBC patients will be enrolled and allocated to placebo or one of two doses of GKT831 (400mg once a day or 400mg twice a day).
- Screening activity has been robust and activated sites have collectively screened over 90 patients to date. However, due to a slower than expected rate of activation of investigational centers in 4 of the 9 involved countries, patient enrollment is taking longer than anticipated. The Company anticipates that the results of the interim analysis will be available Fall 2018, with final results in H1 2019, versus its initial expectation of H1 2018 for interim results and H2 2018 for final results.
- Genkyotex expects that the first Independent Safety Monitoring Board (ISMB) meeting will occur in the first half of May and will report its outcome. The first patients enrolled in the study have now completed the full treatment period. To date, no serious adverse events (SAE), Liver Related Adverse Events (LRAE) or drop outs, have been reported.

Phase 2 trial of GKT831 in patients with diabetic kidney disease

- Patient enrollment in the Phase 2 trial evaluating the safety and efficacy of GKT831 in patients with type 1 diabetes and diabetic kidney disease (DKD) also continues. This investigator-initiated Phase 2 trial is a placebo-controlled, double blind, randomized, parallel group study to evaluate the effect of oral GKT831 on the urine albumin-to-creatinine ratio (UACR) in patients with persistent albuminuria despite treatment with optimal standard of care.
- Patients will receive 200mg of oral GKT831 or placebo twice a day for 48 weeks. A total of 142 patients are planned to be enrolled in the study located in up to 15 investigational centers in Australia. This Phase 2 trial is being fully funded by the Juvenile Diabetes Research Foundation (JDRF) Australia and the Baker Institute.

Research highlights:

- Genkyotex continues the preclinical development of GKT771 and intends to submit a clinical trial application in 2018. GKT771 targets a number of important pathological processes, including angiogenesis, pain processing and inflammation.
- The Company continues to explore the therapeutic value of NOX inhibition in oncology, hearing loss and Parkinson's disease, and to seek opportunities for non-dilutive grant financing to support the preclinical evaluation of drug candidates in these therapeutic areas. In January 2018, academic collaborators published three studies demonstrating the efficacy of GKT831 in preclinical models of diabetic eye and kidney diseases[1-3].
- Data in a preclinical model also showed that GKT831 efficiently targeted cancer associated fibroblasts in prostate cancer and abrogated the pro-tumorigenic influence of the tumor micro-environment. The results of this study, which was conducted by Dr. Natalie Sampson and colleagues at the Medical University of Innsbruck, were published in the International Journal of Cancer (https://doi.org/10.1002/ijc.31316).

References

1. Appukuttan B et al. Effect of NADPH oxidase 1 and 4 blockade in activated human retinal endothelial cells. Clin Exp Ophthalmol. 2018 Jan 23. doi: 10.1111/ceo.13155. [Epub ahead of print]
2. Jeong BY, et al. TGF-β-mediated NADPH oxidase 4-dependent oxidative stress promotes colistin-induced acute kidney injury. J Antimicrob Chemother. 2018 Jan 9. doi: 10.1093/jac/dkx479. [Epub ahead of print]
3. Jeong BY et al. Oxidative stress caused by activation of NADPH oxidase 4 promotes contrast-induced acute kidney injury. PLoS One. 2018 Jan 12;13(1):e0191034. doi: 10.1371/journal.pone.0191034. eCollection 2018.

Conference call

To mark the publication of Genkyotex's Q1 2018 financial information and Business update Elias Papatheodorou, Chief Executive Officer, Philippe Wiesel, Chief Medical Officer and Alexandre Grassin, Head of Finance and Administration are pleased to invite you to a conference call on **Wednesday, April 25, 2018 at 6:00 PM (CEST / Paris time).** To access the conference call, please dial the following number: **+ 33 (0)1 72 72 74 03** and following code: **64460715#**

Upcoming financial event and publication

Genkyotex expects to hold its general assembly on June 13, 2018, and publish its business and cash position update for the 2nd quarter of 2018 on July 25, 2018.

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. A leader in NOX therapies, its unique therapeutic approach is based on a selective inhibition of NOX enzymes that amplify multiple disease processes such as fibrosis, inflammation, pain processing, cancer development, and neurodegeneration.

Genkyotex's platform enables the identification of orally available small-molecules that selectively inhibit specific NOX enzymes. Genkyotex is developing a pipeline of first-in-class product candidates targeting one or multiple NOX enzymes. The lead product candidate, GKT831, a NOX1 and NOX4 inhibitor is evaluated in a phase II clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease) and in an investigator-initiated Phase II clinical trial in Type 1 Diabetes and Kidney Disease (DKD). This product candidate may also be active in other fibrotic indications. Its second product candidate, GKT771, is a NOX1 inhibitor targeting multiple pathways in angiogenesis, pain processing, and inflammation, currently undergoing preclinical testing.

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 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. This partnership could generate up to $57 million in future revenues for Genkyotex, before royalties on sales.[4]

(4) for the risks associated to this specific partnership with Serum Institute, please refer to the section 4.1.7 of the registration document ("*document de reference)* registered by the French Markets Authority (the "AMF") on 29 June 2017 under number R.17-048, "Risks related to development partnerships and to the marketing and sale of product candidates incorporating the Vaxiclase platform".

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

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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 29 June 2017 under number R.17-048., 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.

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