Archamps (France), [April 25, 2019 at 06:00 pm CET]

GENKYOTEX PROVIDES CORPORATE UPDATE AND REPORTS CASH POSITION AT MARCH 31, 2019

- ***Final top-line results of Phase 2 trial of GKT831 for treatment of PBC expected early May 2019***
- ***GKT831 previously generated positive interim results and demonstrated a favorable safety profile throughout the 24-week treatment period***
- ***Cash and cash equivalents of 7.3 million as of March 31, 2019, providing cash runway to April 2020***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today provided a corporate update, and reported cash and cash equivalents of 7.3 million, at March 31, 2019.

Elias Papatheodorou, CEO of Genkyotex, commented: "In the first quarter of 2019, the treatment period of the Phase 2 PBC trial was completed and we expect final top-line data to be available in early May. Importantly, the interim efficacy results presented at the International Liver Conference (ILC) earlier this month support the anti-inflammatory and anti-fibrotic mechanism of action of GKT831."

"We look forward to the initiation of the Phase 2 NIH funded trial in Idiopathic Pulmonary Fibrosis (IPF), which is expected in the coming months," continued Mr. Papatheodorou. "We are excited about the broad therapeutic potential of GKT831 in multiple inflammatory / fibrotic diseases. Furthermore, our cash position allows us to confirm our financial visibility until April 2020."

Clinical highlights

The Company continues the development of its lead product candidate, GKT831, in fibrotic diseases with a focus on three organs: liver, kidney and lung.

Phase 2 clinical trial in Primary Biliary Cholangitis (PBC):

- This is a 24-week, double-blind, placebo-controlled study evaluating the safety and efficacy of GKT831 in patients with PBC and inadequate response to ursodeoxycholic acid (UDCA). A total of 111 PBC patients were enrolled, versus the original target of 102 patients, and allocated to three treatment arms: UDCA plus placebo, UDCA plus GKT831 at 400mg once a day, and UDCA plus GKT831 at 400mg twice a day.
- GKT831 met the primary and secondary interim efficacy endpoints with high statistical significance after only 6 weeks of treatment. While the anti-fibrotic activity of GKT831 will be

assessed at week 24, GKT831 has already exhibited significant anti-cholestatic and anti-inflammatory activity after only 6 weeks of treatment.

- GKT831 exhibited a favorable safety profile throughout the study. There have been no treatment interruptions or premature patient dropouts due to pruritus. Two serious adverse events (SAEs) were reported, a grade 1 urinary infection and multiple bone fractures related to a traffic accident. Both cases were deemed unrelated to GKT831 by the investigators. Treatment was not interrupted, and both patients completed the treatment period as per protocol. GKT831 was also extremely well-tolerated with over 96% of patients completing the full 24-week treatment.
- The previously reported interim efficacy results were presented at the International Liver Congress (ILC2019). The abstract was accepted for oral presentation during the general session and was also selected, via a peer-review process, for inclusion in the "Best of ILC" summary slide deck.
- The last patient completed the full 24-week treatment on March 8, 2019. Top-line-final results are expected in early May 2019.

Investigator-initiated Phase 2 trial in type 1 diabetes and kidney disease (DKD):

- This placebo-controlled, double-blind, randomized, parallel study is evaluating 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. The study continues to enroll patients.
- A total of 142 patients are planned to be enrolled at approximately 15 investigational centers in Australia. This trial is being led by world-renowned diabetes experts, Professor Mark Cooper, Head of Department of Diabetes at Monash University, and Professor Jonathan Shaw, Deputy Director (Clinical and Population Health) at the Baker Heart and Diabetes Institute in Melbourne, Australia.
- The Phase 2 trial is being fully funded by the Juvenile Diabetes Research Foundation Australia and the Baker Institute.

Investigator-initiated Phase 2 trial in patients with idiopathic pulmonary fibrosis (IPF):

- The United States National Institutes of Health awarded an $8.9 million grant to Professor Victor Thannickal at the University of Alabama at Birmingham to fund a multi-year research program evaluating the role of NOX enzymes in IPF, a chronic disease that results in progressive fibrosis of the lungs. The core component of the program is expected to be a 24-week Phase 2 trial of GKT831 in patients with IPF.
- This placebo-controlled, double-blind, randomized, parallel group study will evaluate the safety and efficacy of oral GKT831 in patients with IPF receiving standard of care therapies. A total of 60 patients will be allocated to a 24-week treatment regimen of either oral GKT831 or matching placebo.
- The primary efficacy endpoint will be the change in plasma levels of o,o'-dityrosine, a mechanistic biomarker of protein oxidation, at the end of the 24-week treatment period compared to baseline. Key secondary endpoints include changes in six-minute walk distance, forced vital capacity and high-resolution CT.
- Patient enrollment expected to begin in the coming months.

<u>Research highlights</u>

Genkyotex continues to explore the therapeutic value of NOX inhibition in other therapeutic areas, including oncology. A grant of £260,000 has been awarded by Cancer Research UK (CRUK) to Professor Gareth Thomas of the University of Southampton to support the research program, entitled "Combination immunotherapy for breast cancer: targeting cancer-associated fibroblasts to improving therapeutic vaccination." This is the second grant provided by CRUK to Professor Thomas for the evaluation of NOX

inhibitors in oncology. The Company expects to secure additional non-dilutive grant financing to support its ongoing collaborations with academic partners.

Financial highlights

On March 31, 2019, Genkyotex' cash and cash equivalents totaled 7.3 million vs. €10.3 million on December 31, 2018. The Company's cash burn was primarily driven by investments in the ongoing phase 2 trial in PBC. Genkyotex expects its current resources to support anticipated operations until April 2020.

During the first quarter of 2019, the Company executed a reverse stock split that took effect on March 29, 2019. On that date, every 10 shares with a par value of €0.10 of the Company's issued and outstanding common stock was automatically combined into one share with a par value of €1.00. The number of shares of common stock underlying Genkyotex' options, warrants, convertible securities or other rights to acquire shares of common stock was adjusted accordingly. The ticker symbol (GKTX) remained unchanged. This technical adjustment, purely arithmetical, had no impact on the value of Genkyotex shares held by the shareholders.

Upcoming financial meeting and publication

- June 13, 2019: Annual General Meeting in Paris, France
- July 25, 2019: Business & Cash Position Update 2nd Quarter 2019

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 2 clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease) and in an investigator-initiated Phase 2 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 GKT831 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.

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