Archamps (France), January 31, 2019 at 06:00 pm CET

GENKYOTEX PROVIDES CORPORATE UPDATE AND REPORTS CASH POSITION AT DECEMBER 31, 2018

- ***Over 75% of patients have completed full 24-week treatment period in Phase 2 clinical trial of GKT831 in PBC and no dropouts or treatment interruptions due to pruritus have been reported to date***
- ***Cash and cash equivalents of €10.2 million as of December 31st, 2018, providing cash runway to early 2020***

Genkyotex (Euronext Paris & Brussels: FR0011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today provided a corporate update, and reported cash and cash equivalents of €10.2 million, at December 31st, 2018.

Elias Papatheodorou, CEO of Genkyotex, commented: "*We can confirm that the last patient out in our phase 2 clinical trial in* Primary Biliary Cholangitis (*PBC) is expected by mid-March and that the final results will be available by this Spring. The final results after 24 weeks of treatment will provide key information about the full efficacy profile of GKT831. Pruritus and fatigue are the most critical clinical symptoms and have profound effects on the quality of life of PBC patients. Importantly, no dropouts or treatment interruptions due to pruritus have been reported to date, further enhancing our confidence in the potential of GKT831 to effectively address these key conditions. We expect our current cash position to support our strategic objectives for GKT831 until early 2020, well beyond the completion of the Phase 2 trial in PBC."*

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 PBC patients:
  - The Company announced in November 2018 that GKT831 met the primary and secondary interim efficacy endpoints with high statistical significance after 6 weeks of treatment.
  - To date, all patients have completed at least 12 weeks of treatment and over 75% of the 111 randomized patients have completed the full 24-week treatment period.
  - It is anticipated that the last patients will complete the 24-week treatment period by mid-March 2019.
  - There have been no treatment interruptions or premature patient dropouts due to pruritus to date.
  - The independent safety monitoring board has recommended, following each of its three review meetings, that the study continue as per protocol.

- Genkyotex continues to anticipate that the final results of this study will be available in the spring of 2019.

- The investigator initiated Phase 2 trial in patients with type 1 diabetes and kidney disease continues to enroll patients:
  - This trial is a placebo-controlled, double-blind, randomized, parallel study to evaluate the effect of oral GKT831 on the urine albumin-to-creatinine ratio in patients with persistent albuminuria despite treatment with optimal standard of care.
  - A total of 142 patients are planned to be enrolled at up to 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. As a reminder, the Phase 2 trial is being fully funded by the Juvenile Diabetes Research Foundation Australia and the Baker Institute.
- The investigator initiated Phase 2 trial in patients with idiopathic pulmonary fibrosis (IPF) is expected to begin enrolling patients during the first half of 2019:
  - On July 31, 2018, the Company announced that 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 should be a 24-week Phase 2 trial of GKT831 in patients with IPF.
  - This Phase 2 trial will be a placebo-controlled, double-blind, randomized, parallel group study to 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.

Research highlights

Genkyotex continues to explore the therapeutic value of NOX inhibition in other 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 31, 2018, Genkyotex' cash and cash equivalents totaled €10.2 million vs. €12.8 million on September 30, 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 expected operations until early 2020.

Upcoming financial publication

Genkyotex expects to publish its full-year 2018 financial results on February 28, 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. 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 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. This partnership could generate approximately €150 million in future revenues for Genkyotex, before royalties on sales.

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

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