Archamps (France), March 11, 2019 at 7.00 am CET

GENKYOTEX ANNOUNCES COMPLETION OF 24-WEEK TREATMENT PERIOD OF ITS PHASE 2 TRIAL WITH GKT831 IN PRIMARY BILIARY CHOLANGITIS

- ***Top line results expected in spring 2019***
- ***GKT831 exhibited a favorable safety profile throughout the study***
- ***No drop outs or treatment interruptions due to pruritus***
- ***2 SAEs recorded in the study, both unrelated to GKT831***

Genkyotex (Euronext Paris & Brussels: FR0011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announces today that the last patient has completed on March 8, 2019 the full 24-week treatment in its Phase 2 trial of GKT831 in patients with Primary Biliary Cholangitis (PBC). Positive interim efficacy results after 6 weeks of treatment were previously announced in November 2018. Final results are expected in the spring of 2019. Importantly, final results will include fibrosis and quality of life endpoints.

The safety profile of GKT831 remained favorable throughout the 24-week treatment period. No drop outs or treatment interruptions due to pruritus or fatigue were reported. The study had a very high rate of completion, as 107 out of the 111 randomized patients were treated for the full 24-week period. 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.

"We were extremely encouraged by the positive interim efficacy results announced last November, and our confidence in the potential of GKT831 was further enhanced by the very high completion rate in the study, and the favorable safety profile observed throughout the full 24-week treatment period. We look forward to the final study results which will include quality of life and fibrosis endpoints," **said Philippe Wiesel, Chief Medical Officer of Genkyotex.**

This Phase 2 trial 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 has shown potent anti-fibrotic and anti-inflammatory activity in a broad range of animal models, as well as pharmacodynamic activity in healthy subjects and diabetic patients. Mechanistic data indicate that inhibiting NOX 1 and 4 with GKT831 down regulates multiple fibrogenic pathways, including TGF-β, MCP-1 and ASK1.

"Completing the 24-week treatment period for this extended phase 2 clinical trial is an important milestone for our PBC program and NOX therapeutics. GKT831 continued to demonstrate a favorable safety profile after extended treatment, supporting its anti-inflammatory and anti-fibrotic potential in multiple indications, such as NASH, IPF, diabetic nephropathy, scleroderma, and oncology," **said Elias Papatheodorou, Chief Executive Officer of Genkyotex.**

Genkyotex will present interim efficacy results of its Phase 2 trial of GKT831 for the treatment of PBC during the general session of the International Liver Conference (ILC 2019) in Vienna on April 11, 2019.

Next financial press release:

Q1 2019 business update and cash position: April 25, 2019 (after market)

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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