GENKYOTEX TO PRESENT UPDATED INTERIM RESULTS FROM PHASE 2 TRIAL OF GKT831 IN PRIMARY BILIARY CHOLONGITIS AT 2019 EASL INTERNATIONAL LIVER CONGRESS (ILC)

- Interim results selected for oral presentation and inclusion in “Best of ILC” summary
- All patients have completed treatment; favorable safety profile with no drop outs or treatment interruptions due to pruritus
- Final results at week 24 expected in Spring 2019

Genkyotex (Euronext Paris & Brussels: FR0011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today announced that it will present an update on the previously reported interim efficacy results from its Phase 2 trial of GKT831 in Primary Biliary Cholangitis (PBC) during the 2019 EASL International Liver Congress (ILC), being held in Vienna, from April 10-14.

The abstract has been accepted for oral presentation during general session on April 11, from 2:15-2:30 pm. The presentation, entitled “Efficacy of GKT831 in patients with primary biliary cholangitis and inadequate response to ursodeoxycholic acid: Interim efficacy results of a phase 2 clinical trial”, was also selected, via a peer-review process, for inclusion in the “Best of ILC” summary slide deck. The results to be presented include the effect of GKT831 on markers of cholestasis and inflammation following just six weeks of treatment.

Elias Papatheodorou, CEO of Genkyotex, commented: “We are pleased by the significant interest KOLs are showing in these data, supporting our differentiated novel therapeutic candidate, GKT831. Unlike other drugs that target primarily cholestasis, GKT831 targets the inflammatory and fibrotic components of PBC. While the antifibrotic 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’s mechanism of action has the potential to modify the course of severe diseases in the liver, lungs and the kidneys.”

The Phase 2 trial is a 24-week, double-blind, placebo-controlled study, evaluating the safety and efficacy of GKT831 in patients with PBC following inadequate response to ursodeoxycholic acid (UDCA). A total of 111 PBC patients were enrolled and allocated to three treatment arms: UDCA plus placebo, UDCA plus GKT831 400mg once a day, and UDCA plus GKT831 400mg twice a day. GKT831 has exhibited a particularly favorable safety profile throughout the 24-week treatment period. No drop outs or
treatment interruptions due to pruritus or fatigue were reported. Only two serious adverse events were reported, a grade 1 urinary infection and multiple bone fractures related to a traffic accident. Both cases were deemed unrelated to study drug by the investigators. Final results of the trial at week 24 are expected in Spring 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. 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, or investors@genkyotex.com

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Media relations
Sophie Baumont
LifeSci Advisors
+336 2774 74 49
sophie@lifesciadvisors.com

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