Archamps (France) October 15, 2018 at 07:00 am CEST

Genkyotex Announces Presentation of GKT831 Efficacy Data in a Preclinical Model of Advanced Cholestatic Liver Disease at AASLD Liver Meeting® 2018

- ***GKT831 achieves marked anti-fibrotic effects in clinically relevant model of advanced cholestatic disease***
- ***Interim results of the Phase 2 Clinical Trial with GKT831 in Primary Biliary Cholangitis expected in early November 2018***
- ***Genkyotex to present corporate overview in San Francisco on November 9, 2018***

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today announced that an abstract with preclinical data that demonstrate the activity of GKT831, the Company's lead product candidate, in reversing fibrosis in a MDR2 KO mouse model will be presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) (the Liver Meeting®), which will take place in San Francisco, November 9-13, 2018. The poster will be presented on Saturday, November 10 (2:00 pm–7:30 pm; Presenters Available: 5:30 pm–7:30 pm).

The abstract, entitled "NOX1/4 Inhibition Attenuates Myofibroblast Activation and Liver Fibrosis in MDR2 Deficient Mice, a Model of Progressive Cholangiopathy," will be presented as an oral/poster presentation by Takahiro Nishio, Postdoctoral Scholar at the University of California, San Diego.

"We are looking forward to attending The Liver Meeting®, AASLD's leading Hepatology meeting. This study was conducted in an aggressive type of the MDR2 KO model that is relevant to primary biliary cholangitis (PBC) and primary sclerosing cholangitis," said Philippe Wiesel, M.D., Executive Vice President and Chief Medical Officer of Genkyotex. *"The results demonstrate the ability of GKT831 to induce fibrosis regression in advanced cholestatic disease where currently marketed therapies have been shown to worsen disease activity. These results strengthen our view that GKT831 has the potential to provide therapeutic benefits in a broad patient population, including those with advanced disease and ductopenia."*

Patient enrollment in Genkyotex's Phase 2 clinical trial of GKT831 for the treatment of PBC has been completed. 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 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. Following the recent positive recommendation by the study's Data Safety Monitoring Board, Genkyotex is currently evaluating the possibility of initiating an open-label extension for this Phase 2 trial. The Company expects interim data from this study in early November 2018, with final results anticipated in the Spring of 2019.

Genkyotex to present corporate overview in an AASLD affiliate event for The Liver Meeting® on November 9, 2018 in San Francisco

Genkyotex will present a corporate overview of the Company at an AASLD affiliate event for The Liver Meeting® on November 9, 2018. The event will take place at the W Hotel San Francisco (181 3rd St, San Francisco, CA 94103, USA), from 6:30 to 8:00 am, on November 9, 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 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 (U.S. NIH) of $8.9 million has been 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's 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 has been established with Serum Institute of India Private Ltd (Serum Institute) and could generate approximately €150 million in future revenues for Genkyotex, before royalties on sales.

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

GKTX
LISTED
EURONEXT

ELIGIBLE
PEA
PME

INVESTORS	MEDIA	US
NewCap Dušan Orešanský, Tristan Roquet Montégon and Emmanuel Huynh +33 1 44 71 94 92 genkyotex@newcap.eu	**NewCap** Nicolas Merigeau, Arthur Rouillé +33 1 44 71 00 15 genkyotex@newcap.eu	**LifeSci Advisors, LLC** Brian Ritchie +1-212-915-2578 britchie@lifesciadvisors.com