Archamps (France), May 21st, 2019 at 07:00 am CET

Preclinical study of GKT831 shows rapid regression of cholestatic fibrosis in model of advanced liver fibrosis

PUBLICATION OF GKT831 DATA IN THE *JOURNAL OF HEPATOLOGY*

- ***Data consistent with anti-fibrotic activity recently demonstrated in PBC Phase 2 trial of GKT831***
- ***Data further support broad therapeutic potential of GKT831 in multiple fibrotic diseases***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today announced the publication of preclinical efficacy data with GKT831 for cholestatic fibrosis. The article "Activated Hepatic Stellate Cells and Portal Fibroblasts contribute to cholestatic liver fibrosis in MDR2 knockout mice" was published in the *Journal of Hepatology*[1].

These preclinical results are consistent with the reduction in liver stiffness achieved in Phase 2 with GKT831 after just 24 weeks of treatment in PBC patients. In patients with an estimated F score of F3 (severe) or greater, GKT831 achieved a 21% reduction in liver stiffness. In the 400mg BID dose, GKT831 achieved an absolute reduction of 2.7 kPa compared to an increase of 0.4 kPa for the placebo group.

Philippe WIesel, CMO of Genkyotex, commented: "The MDR2 KO mouse model is the most relevant model of advanced cholestatic fibrosis and is particularly relevant to human diseases like PBC and PSC where patients develop severe fibrosis. The data indicate that GKT831 achieves rapid fibrosis reversal which is in line with the clinical evidence of anti-fibrotic activity obtained in our 24-week PBC trial."

In the MDR2 KO mouse model, GKT831 treatment was initiated at week 12 when advanced liver fibrosis was already established. After only 4 weeks of treatment, GKT831 was able to deactivate myofibroblasts and reverse fibrosis, indicating rapid anti-fibrotic activity.

GKT831 had already shown marked efficacy in multiple mouse models of inflammatory and fibrotic disorders.

1

Nishio T, Hu R, Koyama Y, Liang S, Rosenthal SB, Yamamoto G, Karin D, Baglieri J, Ma HY, Xu J, Liu X, Dhar D, Iwaisako K, Taura K, Brenner DA, Kisseleva T. Activated Hepatic Stellate Cells and Portal Fibroblasts contribute to cholestatic liver fibrosis in MDR2 knockout mice. J Hepatol. 2019 May 6. pii: S0168-8278(19)30273-9. doi: 10.1016/j.jhep.2019.04.012. [Epub ahead of print]

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. or investors@genkyotex.com*

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