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GENKYOTEX'S GKT831 PREVENTS MULTIPLE COMPLICATIONS OF PORTAL HYPERTENSION IN PRECLINICAL MODEL

DATA SUPPORTS THERAPEUTIC ROLE OF GKT831 IN ADVANCED LIVER FIBROSIS

- ***Results published in Clinics and Research in Hepatology and Gastroenterology***
- ***Phase 3 trial being planned in primary biliary cholangitis***

Genkyotex (Euronext Paris & Brussels: FR0013399474 – GKTX), the leading biopharmaceutical company in NOX therapies, today announced the publication of data in Clinics and Research in Hepatology and Gastroenterology showing that its anti-fibrotic drug candidate GKT831, prevents multiple complications of portal hypertension in a preclinical model.

Portal hypertension, the major complication of cirrhosis, develops when advanced liver fibrosis restricts blood flow through the liver. In the face of increased intra-hepatic vascular resistance, portal venous pressure increases and blood flow coming from the bowel and spleen is redirected to the heart through a network of existing and newly formed collateral vessels. This process, called portal-systemic shunting, leads to the development of esophageal varices, enlarged veins prone to bleeding, and also increases cardiac burden. Critically, portal hypertension drives the transition from compensated to decompensated cirrhosis and is responsible for most cirrhosis-related deaths.

Previous preclinical and clinical data indicated that GKT831 has the potential to attenuate portal hypertension by reversing fibrotic remodeling and reducing intrahepatic endothelial dysfunction, which are respectively the structural and dynamic components of portal hypertension.

The published studies were conducted by Wensheng Deng and his colleagues at the Fudan and Jiao Tong Universities in Shanghai. GKT831 administered at 30mg/kg for 14 days following the surgical induction of portal hypertension, was able to prevent the development of complications, including splanchnic angiogenesis, cardiac overload and portal-systemic shunting. The results further demonstrate that NOX1/4 inhibition with GKT831 targets multiple pathways and pathogenic processes underlying progressive liver disease. These beneficial effects of GKT831 correlated with a marked reduction in NOX enzyme activity and reactive oxygen species production.

Philippe Wiesel, CMO of Genkyotex, commented: *"This newly published study shows that NOX1/4 inhibition with GKT831 is also able to reduce the complications of established portal hypertension, and highlights the therapeutic potential of GKT831 in patients with advanced liver disease. These data are consistent with the recently reported efficacy of GKT831 in PBC patients with elevated liver stiffness."*

A final data analysis of a 24-week Phase 2 trial in primary biliary cholangitis (PBC) has shown that GKT831 treatment reduces liver stiffness, which correlates with histologic liver fibrosis. GKT831 at the 400mg twice a day (BID) dose also achieved statistically significant reductions in gamma glutamyl transpeptidase (GGT) and alkaline phosphatase (ALP), which are both markers of cholestatic injury. GKT831 also improved Quality of Life domains important to PBC patients (p<0.002 and p<0.001, respectively). GKT831 was generally safe and well tolerated at all doses. A Phase 3 trial in PBC is being planned.

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the Euronext Paris and Euronext Brussels markets. Its unique platform enables the identification of orally available small-molecules which selectively inhibit specific NOX enzymes that amplify multiple disease processes such as fibrosis, inflammation, pain processing, cancer development, and neurodegeneration.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 has shown evidence of anti-fibrotic activity in a Phase II clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease) and Genkyotex is planning to initiate a Phase III clinical trial in PBC following its positive Phase II results. GKT831 is also being evaluated in an investigator-initiated Phase II 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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