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Genkyotex Announces Positive Outcome from the Independent SMB's Third Pre-Planned Review of the Phase 2 Trial of GKT831 in Primary Biliary Cholangitis

- **Positive safety profile of GKT831 further supported with 87 patients at week 6 and 41 patients now having completed the full 24-week treatment period**
- **Interim efficacy results in early November 2018 and final results in spring 2019**

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies (the “**Company**”), announces today that the independent Safety Monitoring Board (SMB) for its Phase 2 trial of GKT831 for the treatment of Primary Biliary Cholangitis (PBC) held its third pre-planned data review meeting and recommended the continuation of the Company’s trial without protocol amendment.

“This third positive SMB review meeting further supports GKT831’s favorable safety profile in patients with PBC,” said **Philippe Wiesel, Chief Medical Officer of Genkyotex**. *“The SMB assessed safety data collected in 110 patients allocated to GKT831 400mg once a day, GKT831mg twice a day, or placebo. There were 87 patients reviewed who had completed their week 6 visit. Furthermore, 69 subjects had reached week 12 and of these 41 had reached as far as week 24. We now look forward to interim efficacy data from this study, which will be available in early November.”*

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 or UDCA plus one of the two doses of GKT831 (400mg once a day or 400mg twice a day).

Genkyotex continues the preparation of an open-label extension study for patients completing the ongoing Phase 2 trial, as the positive safety profile observed to date supports continued treatment with GKT831 beyond the planned 24 weeks.

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 II clinical trial in primary biliary cholangitis (PBC, a fibrotic orphan disease) and 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. 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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