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# Genkyotex Announces Completion of Enrollment in Interim Analysis Cohort of Phase 2 Trial of GKT831 in Primary Biliary Cholangitis

## *The Company confirms interim results in Fall 2018, and final results in the first half of 2019*

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, announces today that 90 patients have been randomized in its Phase 2 trial of GKT831 for the treatment of Primary Biliary Cholangitis (PBC). This represents the target number of patients required to conduct the pre-planned interim analysis. The analysis will be conducted when these patients have completed 6 weeks of dosing.

*"We are excited to reach this important milestone, which will enable us to conduct the interim analysis in the Fall of this year, as previously planned,"* said Elias Papatheodorou, Chief Executive Officer of Genkyotex. *"Enrollment was robust even during the Summer months, and we wish to thank our investigators and their teams for their outstanding contribution to this important clinical trial. Importantly, the safety profile of GKT831 remains favorable with no serious adverse events and no liver-related adverse events reported to date."*

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 approximately 102 PBC patients will be 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.

### 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. 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 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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