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Genkyotex Announces Positive Outcome from the Second Independent SMB Review of the Phase 2 Trial of GKT831 in Primary Biliary Cholangitis

- ***SMB reviewed 77 patients including 60 who have reached 6 weeks of treatment***
- ***Enrollment in interim analysis cohort of 90 patients has been completed***
- ***Genkyotex to present corporate overview at two U.S. investor conferences***

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, 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 second pre-planned data review meeting and recommended the continuation of the Company's trial without protocol amendment. This second review was based on data collected from 77 randomized patients including at least 60 patients who have completed their week 6 visit. The Company expects interim efficacy results in Fall 2018 and final results in the first half of 2019.

"The positive outcome of this second independent SMB meeting further supports the positive clinical safety profile of GKT831," said Elias Papatheodorou, Chief Executive Officer of Genkyotex. *"The SMB members reviewed all available clinical, pharmacokinetics, and safety laboratory data, from 77 randomized patients including patients who have completed the full 24-week treatment period. The SMB recommended the continuation of the study as per protocol, with no changes or additional data collection required."*

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. To date, more than 90 patients have been enrolled.

Genkyotex also intends to initiate 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. Based on its overall profile, the Company believes that GKT831 has therapeutic potential in a broad range of chronic diseases, including fragile patient populations. In this context, the company recently announced that the United States National Institutes of Health (U.S. NIH) awarded an \$8.9 million grant to Genkyotex's academic collaborators to conduct a clinical trial of GKT831 in patients with idiopathic pulmonary fibrosis (IPF), an aggressive lung disease that results in progressive fibrosis of the lungs.

Genkyotex to Present Corporate Overview at Two U.S. Investor Conferences in September

Genkyotex' CEO, Elias Papatheodorou, will present a corporate overview at two upcoming investor conferences in September: the Rodman & Renshaw 20th Annual Global Investment Conference and the BioCentury 25th Annual NewsMakers in the Biotech Industry Conference.

Rodman & Renshaw 20th Annual Global Investment Conference

Date: Wednesday, September 5
Time: 3:50pm Eastern Time
Location: The St. Regis New York Hotel, New York, NY

BioCentury 25th Annual NewsMakers in the Biotech Industry Conference

Date: Friday, September 7
Time: 9:30am Eastern Time
Location: Millennium Broadway Hotel & Conference Center, New York, NY

Genkyotex will be available for one-on-one meetings around both conferences. If interested, please contact Brian Ritchie of LifeSci Advisors at britchie@lifesciadvisors.com.

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 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 (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 (Vaxicase). 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.



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This press release may contain forward-looking statements by the company with respect to its objectives. Such statements are based upon the current beliefs, estimates and expectations of Genkyotex's management and are subject to risks and uncertainties such as the company's ability to implement its chosen strategy, customer market trends, changes in technologies and in the company's competitive environment, changes in regulations, clinical or industrial risks and all risks linked to the company's growth. These factors as well as other risks and uncertainties may prevent the company from achieving the objectives outlined in the press release and actual results may differ from those set forth in the forward-looking statements, due to various factors. Without being exhaustive, such factors include uncertainties involved in the development of Genkyotex's products, which may not succeed, or in the delivery of Genkyotex's products marketing authorizations by the relevant regulatory authorities and, in general, any factor that could affect Genkyotex's capacity to commercialize the products it develops. No guarantee is given on forward-looking statements which are subject to a number of risks, notably those described in the registration document (document de reference) registered by the French Markets Authority (the AMF) on 27 April 2018 under number R.18-037, and those linked to changes in economic conditions, the financial markets, or the markets on which Genkyotex is present. Genkyotex products are currently used for clinical trials only and are not otherwise available for distribution or sale.

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