

COMMUNIQUÉ DE PRESSE

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GENKYOTEX ANNOUNCES POSITIVE OUTCOME FROM INDEPENDENT SMB'S FIRST PRE-PLANNED REVIEW OF GKT831'S PHASE 2 TRIAL IN PRIMARY BILIARY CHOLANGITIS

- ***Recommendation by Independent Safety Monitoring Board (SMB) to continue trial unchanged following review of safety and pharmacokinetics data***
- ***Results of interim efficacy analysis from Phase 2 trial expected to be available in Fall 2018***

Genkyotex (Euronext Paris & Brussels: FR00011790542 – GKTX), a biopharmaceutical company and the leader in NOX therapies, today announced that the independent Safety Monitoring Board (SMB) for its Phase 2 trial of GKT831 for the treatment of Primary Biliary Cholangitis (PBC) held its first pre-planned data review meeting and recommended the continuation of the Company's trial without protocol amendment. In addition, and as previously indicated, no serious adverse events, liver-related adverse events or drop outs have been reported to date.

"The successful outcome of the first SMB meeting is consistent with the good clinical safety profile of GKT831 observed to date. We are pleased to be able to continue the trial without modification and look forward to the results of the interim efficacy analysis, which are expected this Fall," said Elias Papatheodorou, CEO of Genkyotex.

The first pre-planned SMB meeting was initiated according to the SMB charter. The independent SMB members reviewed all available clinical, pharmacokinetics, and safety laboratory data, including data from 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. A total of 102 PBC patients will be enrolled and allocated to placebo or one of two doses of GKT831 (400mg once a day or 400mg twice a day).

About Genkyotex

Genkyotex is the leading biopharmaceutical company in NOX therapies, listed on the regulated markets of Euronext Paris and Euronext Brussels. 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). 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 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 up to \$57 million in future revenues for Genkyotex, before royalties on sales.⁴

(4) for the risks associated to this specific partnership with Serum Institute, please refer to the section 4.1.7 of the registration document ("document de reference") registered by the French Markets Authority (the "AMF") on 27 April 2018 under number R.18-037, "Risks related to development partnerships and to the marketing and sale of product candidates incorporating the Vaxiclase platform".

For further information, please go to www.genkyotex.com.



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INVESTORS	MEDIA	US
NewCap Dušan Orešanský, Tristan Roquet Montégon and Emmanuel Huynh +33 1 44 71 94 92 genkyotex@newcap.eu	ALIZE RP Caroline Carmagnol & Tatiana Vieira +33 1 44 54 36 65 genkyotex@alizerp.com	LifeSci Advisors, LLC Brian Ritchie +1-212-915-2578 britchie@lifesciadvisors.com